Attachment

PACKAGE INSERT

Paragon CRT™

Manufactured in
Paragon HDS® (paflufocon B)

or

Paragon CRT™ 100

Manufactured in
Paragon HDS® 100 (paflufocon D)

RIGID GAS PERMEABLE CONTACT LENSES FOR 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 law restricts this device to sale by, or on the order of a licensed practitioner.

Contact lenses for Corneal Refractive Therapy 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. 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.

49

Paragon CRT™ and Paragon CRT™ 100
CONTACT LENSES FOR CORNEAL REFRACTIVE THERAPY OVERNIGHT WEAR

DESCRIPTION

Paragon CRT™ contact lenses are manufactured from Paragon HDS® (paflufocon B) and Paragon CRT™ 100 contact lenses are manufactured from Paragon HDS® 100 (paflufocon D). The lenses are designed to have congruent anterior and posterior surfaces each consisting of three zones:

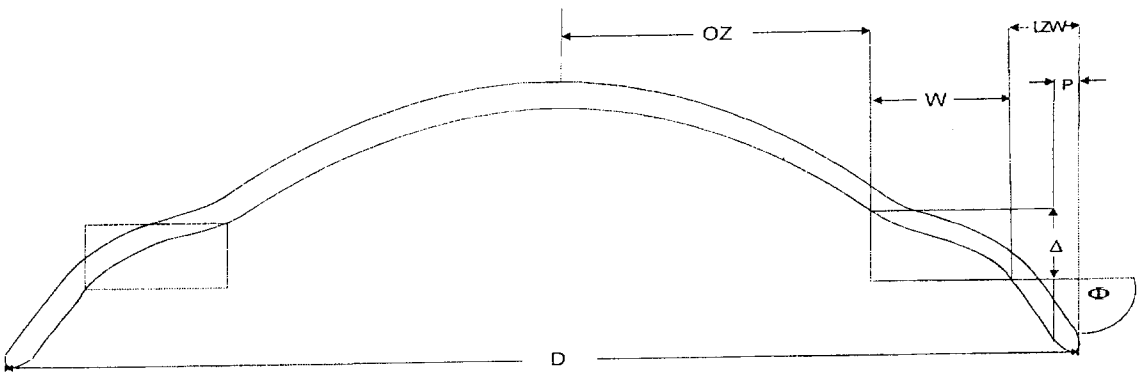
1. The central spherical zone.
2. A mathematically designed sigmoidal corneal proximity "Return Zone".
3. A non-curving "Landing Zone".

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

Paragon CRT™ and Paragon CRT™ 100 Contact Lenses for Corneal Refractive Therapy are to be worn overnight with removal during all or part of each following day. Both materials are 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 Refractive Therapy are available as lathe cut firm contact lenses with blue and green tints. The blue tinted lens contains D&C Green No. 6. The green lens contains D&C Green No. 6 and Perox Yellow No. 9.

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



50

ATTRIBUTES OF THE PARAGON CRT™ LENS (paflufocon B)

Refractive Index	1.449 (Nd at 25°C)
Luminous Transmittance+ (Blue)	95%
Wetting Angle (Receding Angle)	14.7°
Specific Gravity	1.16
Hardness (Shore D)	84
Water Content	<1%

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

ATTRIBUTES OF THE PARAGON CRT™ 100 LENS (paflufocon D)

Refractive Index	1.442 (Nd at 25°C)
Luminous Transmittance+ (Green)	95%
Wetting Angle (Receding Angle)	42°
Specific Gravity	1.10
Hardness (Shore D)	79
Water Content	<1%

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

OXYGEN PERMEABILITY - CRT™ LENS DESIGN

Material	Power	Oxygen Permeability (Revised Fatt Method*) Dk x 10^{-11}	Oxygen Permeability (ISO Method**) Dk x 10^{-11}	Center Thickness (mm)	Harmonic Mean Thickness*** (mm)	Oxygen Transmissibility (Fatt) Dk/l x10^{-9}	Oxygen Transmissibility (ISO) Dk/l x10^{-9}
HDS 100	-2.00	145	100	0.145	0.163	89	61
HDS 100	Plano	145	100	0.163	0.166	87	60
HDS 100	+2.00	145	100	0.180	0.168	86	60
HDS	-2.00	58	40	0.124	0.148	39	27
HDS	Plano	58	40	0.147	0.149	39	27
HDS	+2.00	58	40	0.169	0.161	36	25

* (cm^2/sec) (mL O_2)/ (mL x mm Hg) Revised Method of I. Fatt
** (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 CRT™ and Paragon CRT™ 100 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 CRT™ and Paragon CRT™ 100 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 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.

61

INDICATIONS (USES)

Paragon CRT™ (paflufocon B) and Paragon CRT™ 100 (paflufocon D) 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 CRT™ or Paragon CRT™ 100 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 CRT™ and Paragon CRT™ 100 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 CRT™ and Paragon CRT™ 100 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,

S2

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 CRT™ and Paragon CRT™ 100 contact lenses manufactured from Paragon HDS® and Paragon HDS® 100 respectively 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 CRT™ and Paragon CRT™ 100 lens is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in Unique-pH™ Multi-Purpose Solution. This solution contains hydroxypropyl guar, a unique wetting and conditioning polymer system, polyethylene glycol, Tetronic*, boric acid, propylene glycol; and, is preserved with POLYQUAD® (polyquarternium-1) 0.0011% and edetate disodium 0.01%. 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 unpreserved saline prior to cleaning, disinfecting and dispensing.

* Registered Trademark of BASF corp.
Unique-pH™ is a Trademark of Alcon Laboratories, Inc.

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). If the lens is stored for longer periods of time, it should be cleaned and disinfected with a recommended product (see product list in the Lens Care Directions section), 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 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.

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, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- 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

INTRODUCTION

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.

DEMOGRAPHIC INFORMATION

A total of 205 subjects (408 eyes) were enrolled and treated comprising of 188 Caucasians, 1 African American, 13 Asian/Pacific Islanders, and 3 Hispanics. Data on 121 subjects (240 eyes) were analyzed following 9 months of treatment. There were 73 female and 48 male patients. The mean age of these subjects was 35 years (ranging from 12 to 56 years).

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.

S6

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 VA 20/20 or better **	FINAL VA 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)

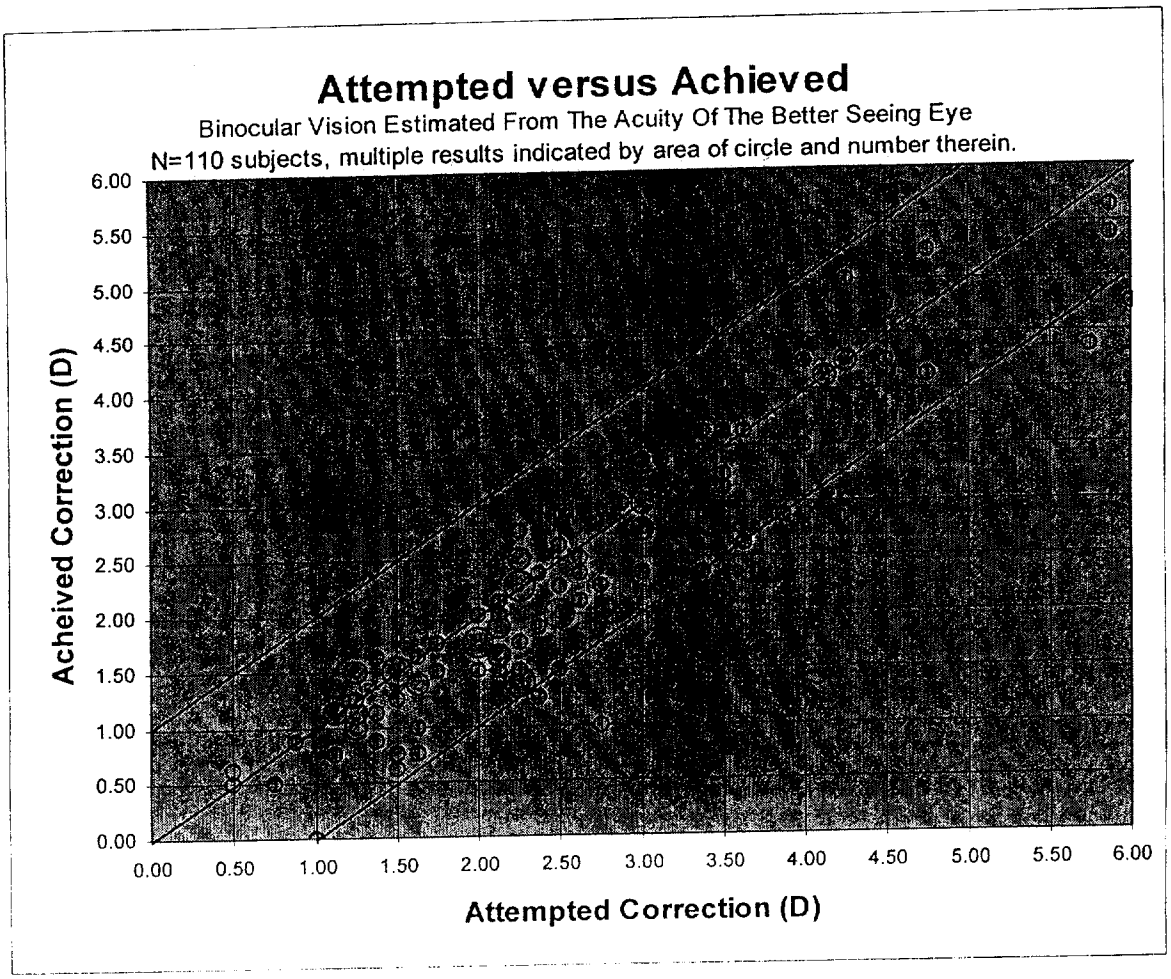
Accuracy

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 myopia 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 below graphically depicts the accuracy of the treatment.

[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

57



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 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 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 value found in the cell identified in this way represents the average number of hours that similar patients have experienced before

98

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.

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.

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

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, 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.

S9

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.

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

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 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).

FITTING

Note: Contact lenses for Corneal Refractive Therapy 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 CRT™ and Paragon CRT™ 100 Contact Lenses for Contact Lens Corneal Refractive Therapy. For a description of fitting techniques, refer to the Professional Fitting And Information Guide - Paragon CRT™ and Paragon CRT™ 100. Copies are available from:

Paragon Vision Sciences
947 E. Impala Avenue
Mesa, Arizona 85204-6619

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 CRT™ and Paragon CRT™ 100 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 CRT™ and Paragon CRT™ 100 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

The following is a list of products available for use with Paragon CRT™ and Paragon CRT™ 100 rigid gas permeable contact lenses. This is not an exclusive list. You may use other lens care solutions as recommended by your eye care practitioner.

SYSTEM PROCESS	CHEMICAL (not heat) DISINFECTION SYSTEM
Cleaning	Unique-pH™ Multi-Purpose Solution, SupraClens®, Opti-Clean® II, Opti-Zyme®, Barnes-Hind® GP Daily Cleaner, LC-65®, Pro-Free/GP®
Disinfection	Unique-pH™ Multi-Purpose Solution, Barnes-Hind® GP Wetting and Soaking Solution, Wet-N-Soak® Plus
Lubrication	Clerz® Plus, Opti-Tears®, Refresh Contacts™, Wet-N-Soak® Rewetting Drops

PRODUCT LIST

Unique-pH™ Multi-Purpose Solution, SupraClens®, Clerz® Plus, Opti-Clean® II, Opti-Zyme®, Opti-Tears® by Alcon Laboratories, Inc.

Barnes-Hind® GP Daily Cleaner, LC-65®, ProFree/GP®, Barnes-Hind® GP Wetting and Soaking Solution, Wet-N-Soak® Plus, Wet-N-Soak® Rewetting Drops by Allergan Pharmaceuticals

The directions found in the package inserts from these products should be followed. 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 CRT™ and Paragon CRT™ 100 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.
- Clean one lens first. The recommended procedure is to always clean the same lens first to avoid mix-ups. Rinse the lens thoroughly 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.

62

- 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 CRT™ and Paragon CRT™ 100 lens is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in Unique-pH™ Multi-Purpose Solution. This solution contains hydroxypropyl guar, a unique wetting and conditioning polymer system, polyethylene glycol, Tetronic*, boric acid, propylene glycol; and, is preserved with POLYQUAD® (polyquarternium-1) 0.0011% and edetate disodium 0.01%. The case, packing slip or invoice is marked with the central base curve radius, diameter, dioptric power, overall diameter, Return Zone Depth, Landing Zone Angle, center thickness, serial number, ship date and the color of the lens.

* Registered Trademark of BASF corp.
Unique-pH™ is a Trademark of Alcon Laboratories, Inc.

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). If the lens is stored for longer periods of time, it should be cleaned and disinfected with a recommended product (see product list in the Lens Care Directions section), 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
947 E. Impala Avenue
Mesa, Arizona 85204-6619

1-800-528-8279
1-480-892-7602
1-480-926-7369 FAX

(Print date)

PROFESSIONAL FITTING AND INFORMATION GUIDE

Paragon CRT™

Manufactured in
Paragon HDS® (paflufocon B)

or

Paragon CRT™ 100

Manufactured in
Paragon HDS® 1OO (paflufocon D)

RIGID GAS PERMEABLE
CONTACT LENSES
FOR
CONTACT LENS CORNEAL REFRACTIVE THERAPY

OVERNIGHT WEAR

TABLE OF CONTENTS

INTRODUCTION

Paragon CRT™ and Paragon CRT™ 100 Contact Lenses for Corneal Refractive Therapy produce a temporary reduction of myopia by reversibly altering the curvature of the cornea. The Paragon CRT™ and CRT™ 100 contact lenses are manufactured from Paragon HDS® and Paragon HDS® 100 respectively. A slight reduction of the curvature of the cornea can reduce the excessive focusing power of the myopic eye. If the amount of corneal reshaping is precisely controlled as is the objective of the CRT™ lens design, it is possible to bring the eye into correct focus and completely compensate for myopia. After the contact lens is removed, the cornea retains its altered shape for all or most of one's waking hours. The lens is designed to be worn overnight with removal during following day. The Paragon CRT™ and Paragon CRT™ 100 lenses must be worn at night on a regular schedule to maintain the corneal reshaping, or the pre-treatment myopia will return.

PRODUCT DESCRIPTION

Paragon CRT™ contact lenses are manufactured from Paragon HDS® (paflufocon B) and Paragon CRT™ 100 contact lenses are manufactured from Paragon HDS® 100 (paflufocon D). 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 CRT™ and Paragon CRT™ 100 Contact Lenses for Corneal Refractive Therapy are to be worn overnight with removal during all or part of each following day. Both materials are 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 Refractive Therapy are available as lathe cut firm contact lenses with blue and green tints. The blue tinted lens contains D&C Green No. 6. The green lens contains D&C Green No. 6 and Perox Yellow No. 9.

Detailed Description

Generally the central base curve is chosen to be flatter than the curvature of the central cornea by an amount such that if the cornea were to take on this lens curvature a significant reduction in myopia would be expected. The lens is fitted to allow this zone to contact the central corneal apex. Until such time as the cornea has taken on the curvature of this zone of the lens, it is expected that this zone will gradually diverge from the corneal curvature, thus rising away from it with a maximum deviation at the edge of the zone.

The first zone peripheral to the central base curve, the Return Zone, has a sigmoidal shape that smoothly joins this zone to the central zone and the third element. The sigmoid will be mathematically designed to return the posterior lens surface to closer proximity to the cornea than it would have had if the geometry of the central base curve were continued through this zone. This zone is conveniently described by referring to the width and depth of a rectangle which would enclose a cross section through the Return Zone (see drawing page 4). The width of the zone is fixed at 1 mm while the fitter determines the Return Zone Depth (RZD).

The third element, referred to as the Landing Zone, has the form of a truncated cone and is concentric to the Return Zone. This element is intended to be tangential to the cornea at a specified diameter but not initially in contact with it. Since the Landing Zone naturally deviates from the cornea peripheral to the point of tangential correspondence, there is no need for an additional peripheral curve to give "edge lift". Fluid forces arising from the approximation of Landing Zone and cornea participate with other factors in stabilizing the lens orientation on the eye. The Landing Zone is characterized by the angle that its cross section makes with the horizontal and by its chord diameter; both parameters are selected by the fitter.

8L

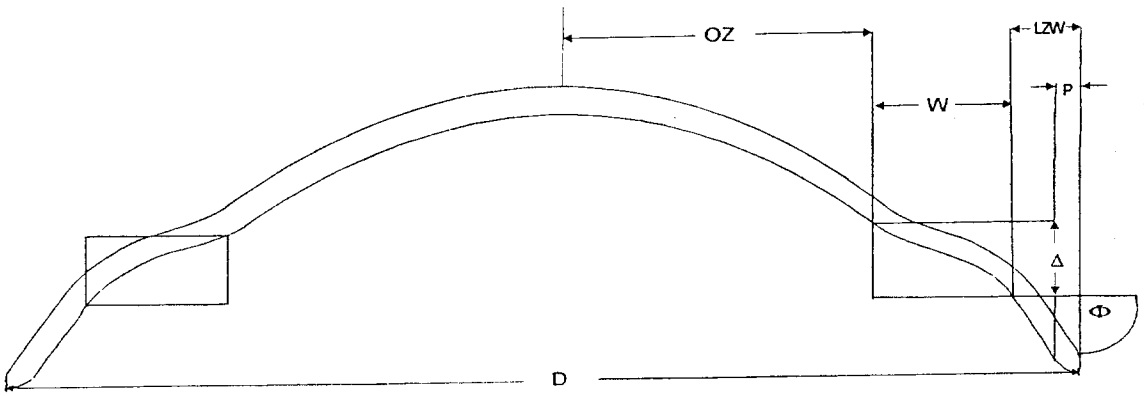
The last and most peripheral element, the edge terminus, deviates from the uncurved Landing Zone and curves away from the underlying cornea to merge with the anterior surface thereby forming the edge of the lens. This zone follows the prescribed shape of a convex ellipse thereby "rolling" the lens surface away from the cornea promoting comfort. This terminus is not to be confused with a "peripheral curve" frequently found in RGP designs. Such peripheral curves are concave toward the cornea with a radius specified to maintain nearly parallel alignment with it. Such lenses also have a separate edge contour, which is created by grinding and polishing the edge but its shape is typically arbitrarily derived by the nature of the processes and lens edge thickness. The CRT™ edge is pre-specified and equivalent in all lenses regardless of their other parameters.

Paragon CRT™ and Paragon CRT™ 100 contact lenses are used to temporarily reshape the cornea to change its refractive power with a resultant reduction in the pretreatment refractive error. Corneal tissue is redistributed without significant alteration of its physiology. The change in shape is the result of gentle mechanical pressure from the flattened central zone of the lens augmented by the availability of unoccupied volume beneath the Return and Landing Zones of the lens. After wearing of the lens, the cornea typically demonstrates an increased radius of curvature in the central area and a decreased radius of curvature in the paracentral area allowed by the clearance within the outer portion of the optic zone and the Return Zone of the lens.

Although rarely required, the anterior central curve is selected to provide any necessary optical power to correct residual refractive error not corrected by the optical and mechanical effect of the posterior base curve and the tear lens formed between it and the cornea. Typically this surface and the other anterior surfaces exactly parallel their posterior counterparts. Lens thicknesses in the three zones are not dependent on lens parameters but have been selected to maximize oxygen transmission, stability and comfort.

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
Edge Terminus Width (P)	0.04 mm to LZW
Dioptric Powers	-2.00 to +2.00 Diopters



85

ATTRIBUTES OF THE PARAGON CRT™ LENS (paflufocon B)

Refractive Index	1.449 (Nd at 25°C)
Luminous Transmittance+ (Blue)	95%
Wetting Angle (Receding Angle)	14.7°
Specific Gravity	1.16
Hardness (Shore D)	84
Water Content	<1%

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

ATTRIBUTES OF THE PARAGON CRT™ 100 LENS (paflufocon D)

Refractive Index	1.442 (Nd at 25°C)
Luminous Transmittance+ (Green)	95%
Wetting Angle (Receding Angle)	42°
Specific Gravity	1.10
Hardness (Shore D)	79
Water Content	<1%

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

OXYGEN PERMEABILITY - CRT™ LENS DESIGN

Material	Power	Oxygen Permeability (Revised Fatt Method*) Dk x 10^{-11}	Oxygen Permeability (ISO Method**) Dk x 10^{-11}	Center Thickness (mm)	Harmonic Mean Thickness*** (mm)	Oxygen Transmissibility (Fatt) Dk/l x 10^{-9}	Oxygen Transmissibility (ISO) Dk/l x 10^{-9}
HDS 100	-2.00	145	100	0.145	0.163	89	61
HDS 100	Plano	145	100	0.163	0.166	87	60
HDS 100	+2.00	145	100	0.180	0.168	86	60
HDS	-2.00	58	40	0.124	0.148	39	27
HDS	Plano	58	40	0.147	0.149	39	27
HDS	+2.00	58	40	0.169	0.161	36	25

* (cm^2/sec) (mL O_2)/ (mL x mm Hg) Revised Method of I. Fatt
** (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 CRT™ and Paragon CRT™ 100 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 CRT™ and Paragon CRT™ 100 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 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.

86

INDICATIONS (USES)

Paragon CRT™ (paflufocon B) and Paragon CRT™ 100 (paflufocon D) 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 lens wear must be continued on a prescribed wearing 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)

Reference the so entitled section found in the enclosed Package Insert.

WARNINGS

Reference the so entitled section found in the enclosed Package Insert.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

Reference the so entitled section found in the enclosed Package Insert.

PRECAUTIONS

Reference the so entitled section found in the enclosed Package Insert.

SELECTION OF PATIENTS

Patients are selected who have a demonstrated need and desire for a refractive reduction by Contact Lens Corneal Refractive Therapy with rigid gas permeable contact lenses and who do not have any of the contraindications for contact lenses previously described. Paragon CRT™ and Paragon CRT™ 100 Contact Lenses for Corneal Refractive Therapy are indicated for myopic patients who desire not to wear vision correction devices during the daytime hours, but still require the ability to see clearly during that time.

Paragon CRT™ and Paragon CRT™ 100 contact lenses for overnight Contact Lens Corneal Refractive Therapy are primarily intended for patients who are within the following parameters.

Refractive Error	-0.5 to -5.50 diopters with up to –1.75 diopters of astigmatism
Keratometry	37 to 52 diopters
Visual Acuity	20/20 to 20/1000

FITTING CONCEPT

Paragon CRT™ and Paragon CRT™ 100 Contact Lenses for Corneal Refractive Therapy are intended to be fitted so as to flatten the central cornea and thereby reduce myopia. This goal is accomplished by the lens design and the manner in which the lens is fitted. The goal in fitting is a well-centered lens having a base curve that is flatter than the flattest meridian of the cornea by at least the attempted treatment power in that meridian. A well-fit lens will have proper sagittal depth to prevent z-axis tilt and achieve centration over the corneal apex. A well-fit lens will also have a proper sagittal depth profile to prevent bearing at the Return Zone – Landing Zone junction or heavy bearing in the periphery of the lens. The lens will demonstrate central corneal applanation, paracentral lens-cornea clearance and Landing Zone-cornea tangential correspondence.

87

The Paragon CRT™ and Paragon CRT™ 100 Contact Lens Corneal Refractive Therapy fitting system utilizes the following fixed parameters.

- Optic Zone = 6.0 mm
- Return Zone Width = 1.0 mm
- Center thickness = 0.15 mm + 0.01

The optic zone and Return Zone Width may be changed in rare circumstances by means of a special order. Smaller optic zones may be appropriate in unusually small corneal diameters and in the case of target reductions greater than 5.00 diopters. For corneal diameters greater than 10.8 mm and target improvements less than 5.00 diopters, the standard parameters are recommended.

There are four primary fitting objectives:

- Provide a base curve that will reshape the underlying cornea to a resultant curvature that produces emmetropia or low hyperopia.
- Provide an initial clearance at the point of tangential correspondence of the Landing Zone and peripheral cornea that will allow the corneal apex to retreat approximately 6 microns per diopter of treatment.
- Provide a Landing Zone that has the proper angle to provide a midpoint of tangency to the underlying cornea near the midpoint of the zone itself.
- Provide a lens diameter that, in conjunction with the Landing Zone Angle, provides optimum centration.

The Paragon CRT™ and Paragon CRT™ 100 contact lenses in conjunction with the following fitting procedure can fulfill these objectives.

Predicting Lens Results

Clinical studies have not established reliable methods to predict which patients will achieve the greatest corneal flattening with these contact lenses for Corneal Refractive Therapy.

Paragon CRT™ and Paragon CRT™ 100 Contact Lenses for Corneal Refractive Therapy may produce a temporary reduction of all or part of a patient's myopia. The amount of reduction will depend on many factors including the amount of myopia, the elastic characteristics of the eye and the way that the contact lenses are fitted. Average amounts of reduction have been established by clinical studies but the reduction for an individual patient may vary significantly from the averages.

CLINICAL STUDY DATA

Reference the so entitled section found in the enclosed Package Insert.

RISK ANALYSIS

There is a small risk involved when any contact lens is worn. It is not expected that Paragon CRT™ or Paragon CRT™ 100 contact lenses for orthokeratology will provide a risk that is greater than other rigid gas permeable contact lenses.

The two most common side effects, which occur in rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that these two side effects will also occur in some wearers of Paragon CRT™ or Paragon CRT™ 100 contact lenses for orthokeratology. Other side effects, which sometimes occur in all hard contact lens wearers are pain, redness, tearing, irritation, discharge, abrasion of the eye or distortion of vision. These are usually temporary conditions if the contact lenses are removed promptly and professional care is obtained. When overnight orthokeratology lenses dislocate during sleep, transient distorted vision may occur the following

morning after removal of the lenses. This distortion may not be immediately corrected with spectacle lenses. The duration of distorted vision would rarely be greater than the duration of the daily visual improvement normally achieved with the lenses.

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

FITTING PARAGON CRT™ AND PARAGON CRT™ 100 CONTACT LENSES FOR CORNEAL REFRACTIVE THERAPY

Note: Contact lenses for Corneal Refractive Therapy should be fitted only by a trained and certified contact lens fitter.

Fitting Option I

Slide Rule Calculator

Utilizing a provided slide rule calculator, practitioners will cross-reference a patient's flat Keratometric value and their vertexed Manifest Refraction Sphere (MRS) and thereby will determine a suggested diagnostic lens from an in-office diagnostic/dispensing lens system.

The slide rule will suggest a specific lens including the parameters of Base Curve, Return Zone Depth (RZD) and Landing Zone Angle (LZA) for initial evaluation by the practitioner. Based on the results of fluorescein pattern evaluation of the suggested lens, the practitioner may move to other lenses in the dispensing system to determine the best fit lens for dispensing to the patient.

The slide rule will calculate the Base Curve for 0.00 Target as follows:

Calculation Treatment Base Curve

Flat K (in diopters)
- MRS
- 0.50 Adjustment
= Base Curve

Calculated Base Curve	
43.75	FK
+ 0.00	TGT
43.75	
- 4.00	MRS (Vertexed)
39.75	
- 0.50	Rx = +0.50
39.25	**Base Curve**

In the above example, the slide rule will suggest the following lens from the diagnostic/dispensing set for initial evaluation.

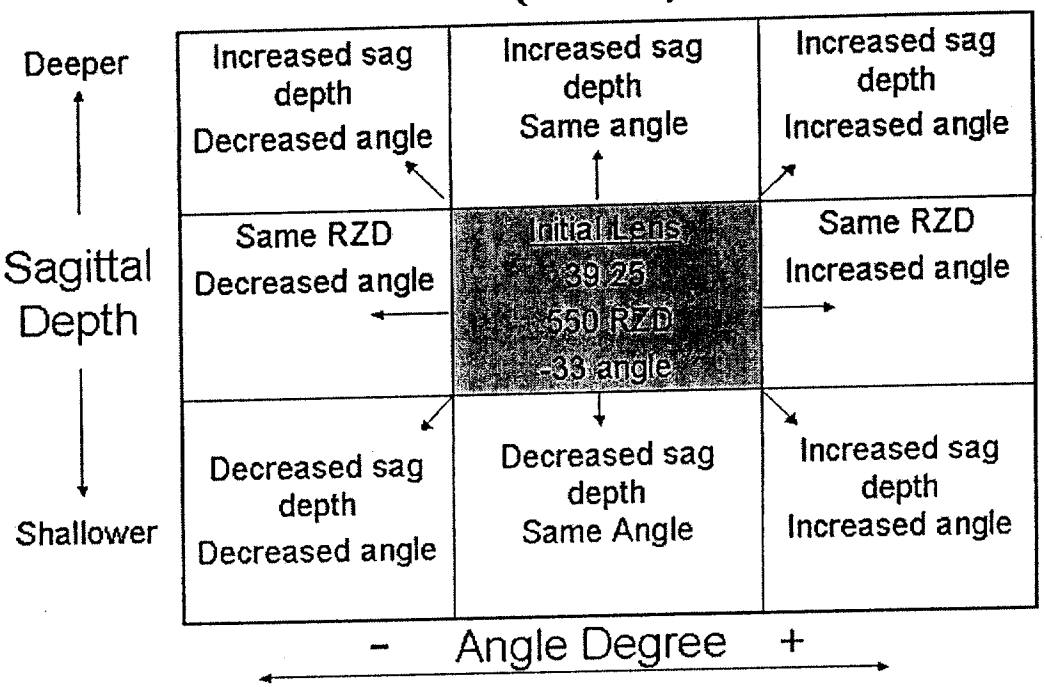
Choose Trial Lens

Look for this lens in the Trial Set and evaluate for "Dispensability".

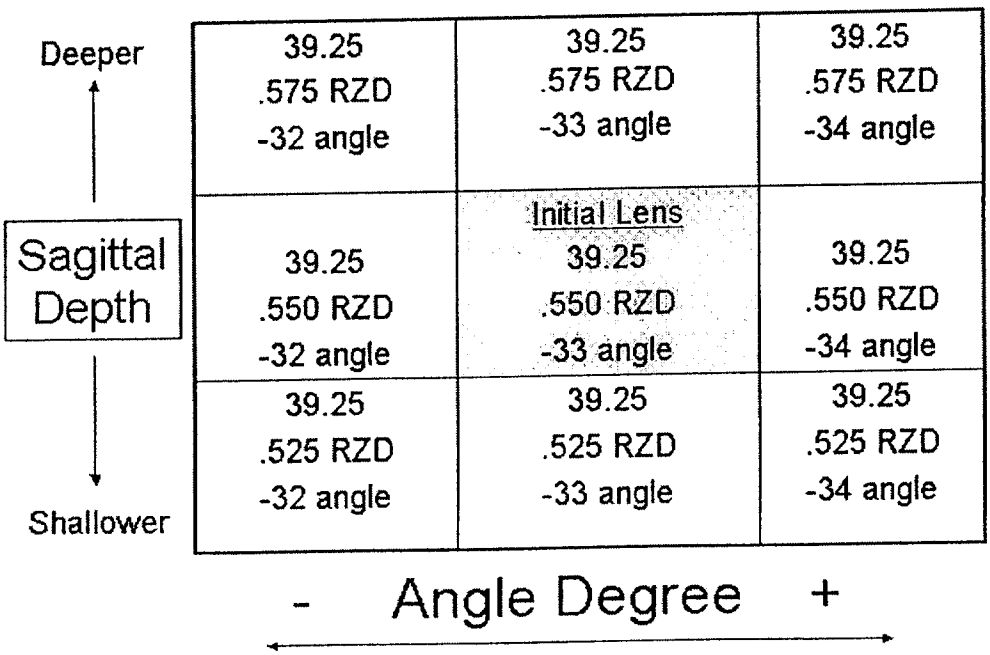
39.25 BC **0.550** RZD **- 33** LZA

89

39.25 (8.60)B.C.



39.25 (8.60)B.C.



90

39.25 (8.60)B.C.

With shallower Lens in place:

1. Does it still center?
2. If Yes....
3. Evaluate Edge Lift

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	Initial Lens 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

\- Angle Degree +

39.25 (8.60)B.C.

With Indicated Lens in place:

1. If No....
2. Return to Initial lens and evaluate edge lift

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	Initial Lens 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 ↑ .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

\- Angle Degree +

39.25 (8.60)B.C.

With Initial Lens in place:
Evaluate Edge lift

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	Initial Lens 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

\- Angle Degree +

39.25 (8.60)B.C.

With Initial Lens
Lens in place:

1. Does it center?
2. If No....
3. Increase RZD

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	Initial Lens 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

\- Angle Degree +

39.25 (8.60)B.C.

With Lens in place:

1. Does it center?
2. If Yes....
3. Evaluate Edge Lift

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	Initial Lens 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

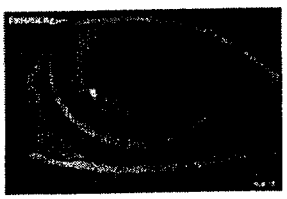
Sagittal Depth

\- Angle Degree +

39.25 (8.60)B.C.

With Increased RZD Lens in place:

1. Does it center?
2. If No....
3. Increase Angle



39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	Initial Lens 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

\- Angle Degree +

39.25 (8.60)B.C.

With Increased angle lens in place:

1. Does it center?
2. Yes
3. Dispense

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	Initial Lens 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

- Angle Degree +

39.25 (8.60)B.C.

With Lens in place:

1. Does it center?
2. If No....
3. Custom Lens

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	Initial Lens 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

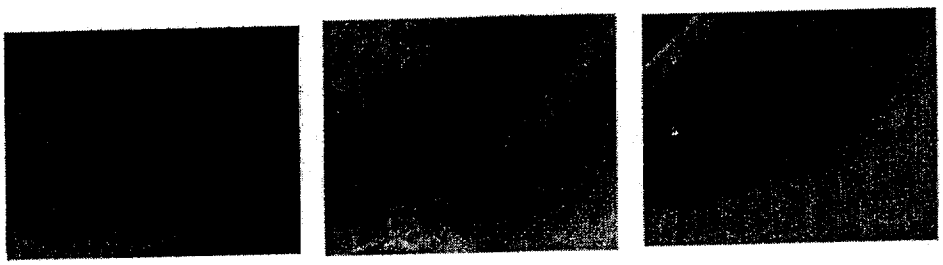
- Angle Degree +

GL

Evaluate Edge Lift

When you have found the shallowest lens *that centers-* evaluate edge lift.

With shallowest RZD lens that centers- Evaluate Edge Lift



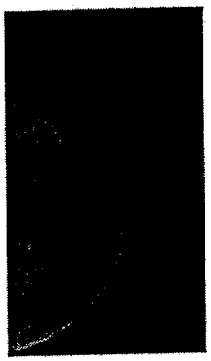
Excessive Edge Lift-
Increase angle

Good Edge Lift
Dispense

Insufficient Edge Lift
Decrease edge lift

QC

39.25 (8.60)B.C.



1. Excessive Edge Lift?
2. If Yes....
3. Increase Angle

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	Initial Lens 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

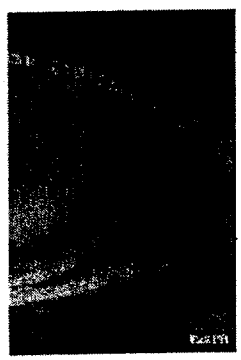
Sagittal Depth

- Angle Degree +

Shallowest RZD *with centration*

39.25 (8.60)B.C.

1. Good Edge Lift?
2. If Yes...
3. Dispense



39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	Initial Lens 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

- Angle Degree +

96

39.25 (8.60)B.C.

1. Insufficient Edge Lift?
2. If Yes....
3. Decrease Angle

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	Initial Lens 39.25 .550 RZD -33 angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

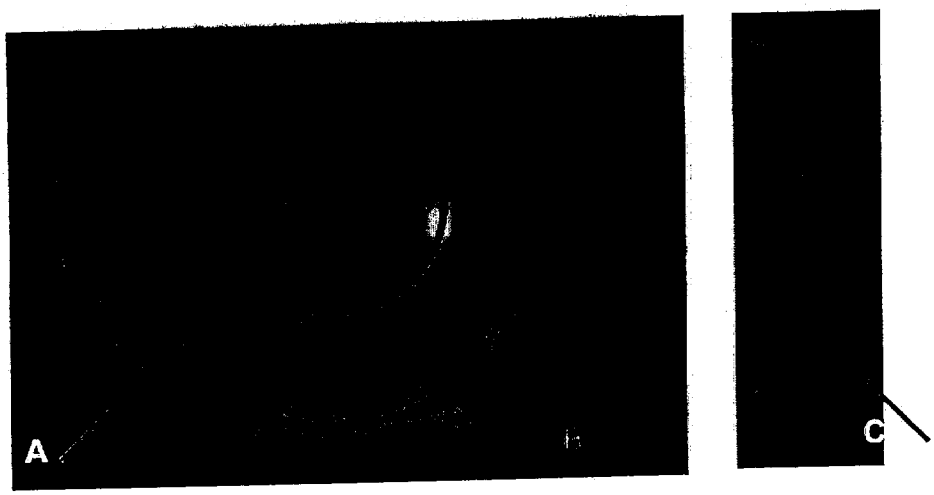
\- Angle Degree +

9

Dispensability

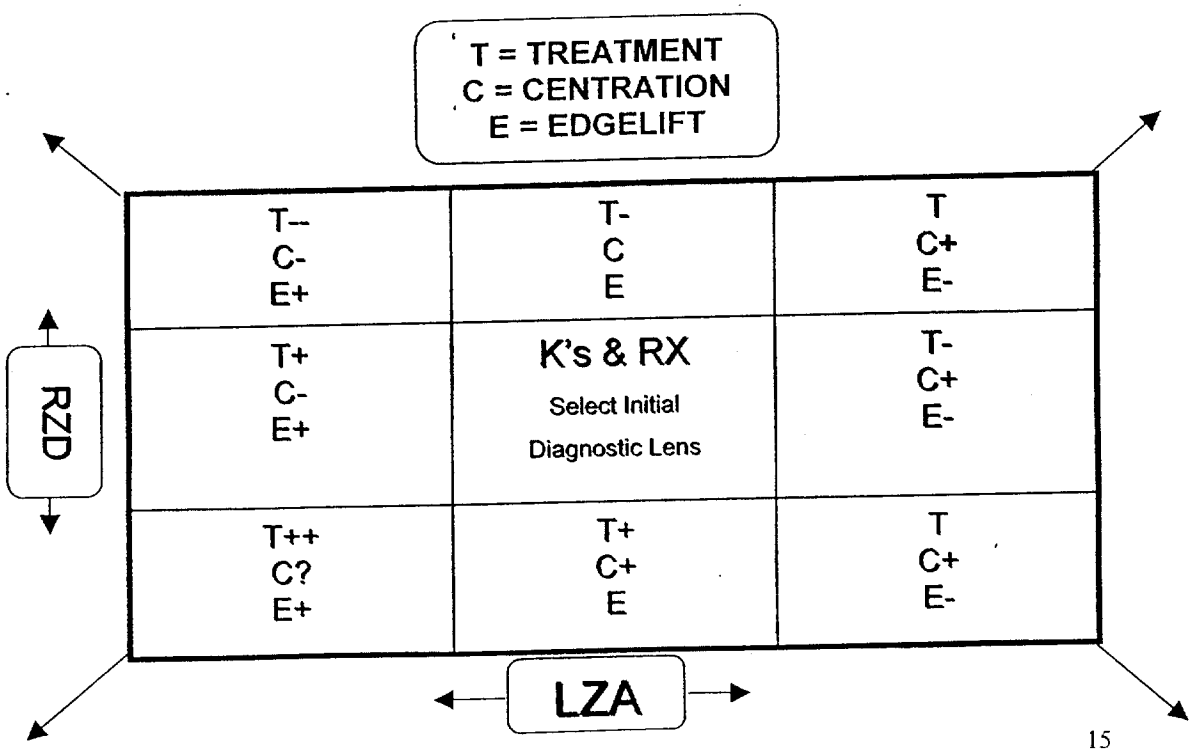
The lens should present with:

- 4+ mm Treatment Zone *(see below illustration)*
- Centered, limbus-to-limbus and in relation to pupil *(see below illuistration)*
- Acceptable Edge Lift *(note A, B, C arrows in below illustration)*
- More than "Just Landed" Appearance; "JL" to moderately heavy landing is acceptable
- Fluorescein reveals a "Black, Green, Black, Green" pooling pattern



A: **minimal edge lift, however, acceptable**
B: **more edge lift than necessary, but OK as is**
C: **optimum edge lift appearance**

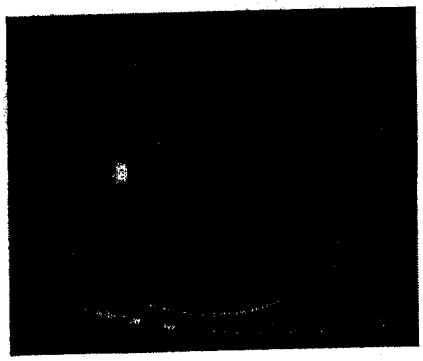
The Diagnostic/Dispensing system suggested an initial lens and based on observation, the clinician moves to centration, additional treatment and appropriate edge lift by moving to other lenses, if necessary, within the same Base Curve range, based on the following parameter options.



98

The lens is *NOT* dispensable when any of these problems exist:

- Small or NO treatment zone
- Decentered lens
- Minimal edge lift or seemingly tight periphery (LZA is excessive)



Small Treatment Zone resulting from sag too deep.

No Treatment Zone; Excessive pooling of Fluorescien centrally resulting from sag too deep.

Oval Treatment Zone with "Just Landed" appearance resulting from sag to deep; if zone is circular, both major

99

How To Fix Fitting Problems

Small or No Treatment Zone

First option	decrease LZA
Second option	flatten Base Curve
Third option	decrease RZD

Decentered Lens

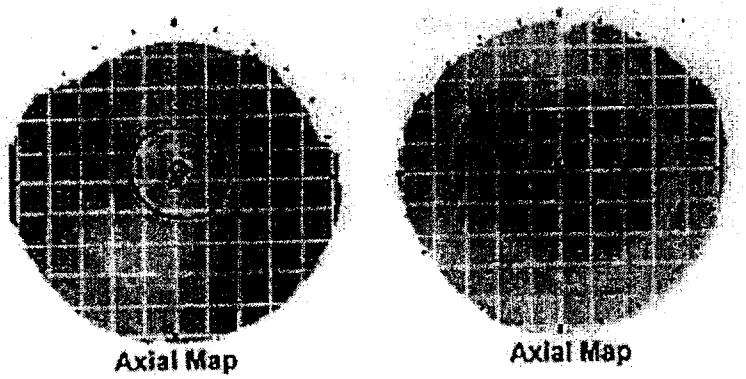
If inferior & nasal	decrease LZA
If inferior & centered (or slightly temporal)	decrease LZA *and if remains decentered, increase RZD*
If superior & nasal	decrease LZA *and if remains decentered, increase RZD*
If superior & centered laterally **	increase RZD

Minimal edge lift or seemingly tight periphery (LZA is excessively "heel down") **

First option	decrease LZA

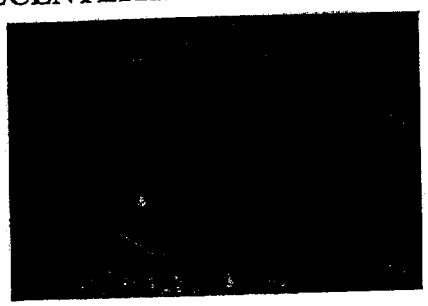
** "Z" Axis tilt may occur if the LZA is 2 degrees too great. Sometimes this will cause a superiorly decentered lens showing excessive fluorescein pooling from the RZD all the way to the edge of the lens. Decrease the LZA by 2 degrees and increase the RZD (25 to 50 microns) if this occurs.

WELL-CENTERED LENS BEFORE & AFTER

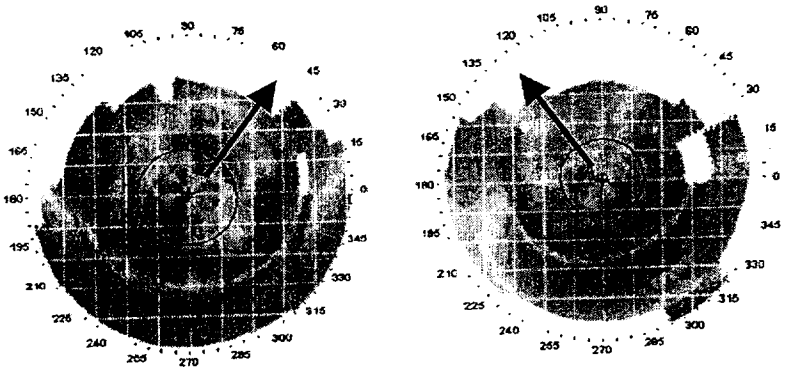


100

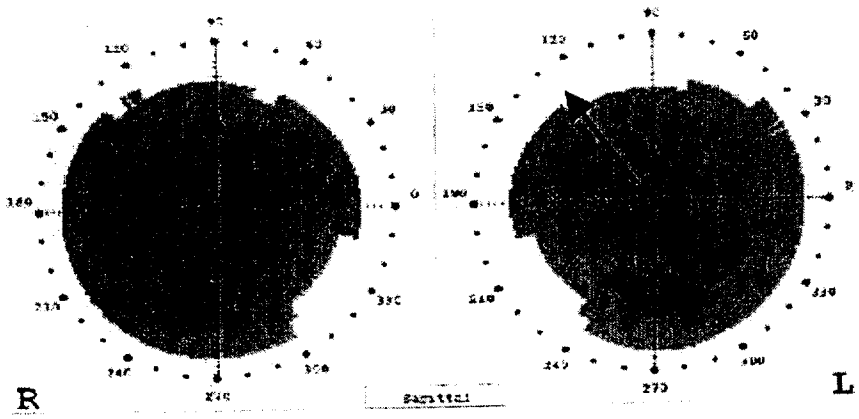
DECENTERED LENS EXAMPLES



Superiorly Riding (with oval treatment zone)

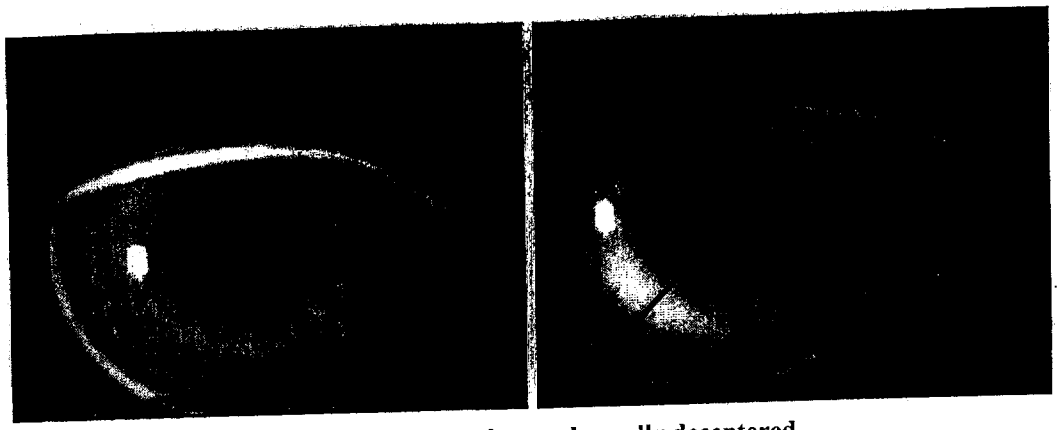


Both lenses are riding superiorly and slightly nasal, confirmed by topography. Note the inferior and steep "smile" (epithelium being pushed inferiorly from the high riding lens) and the "up and in" displacement of the steeper central zone (central island).

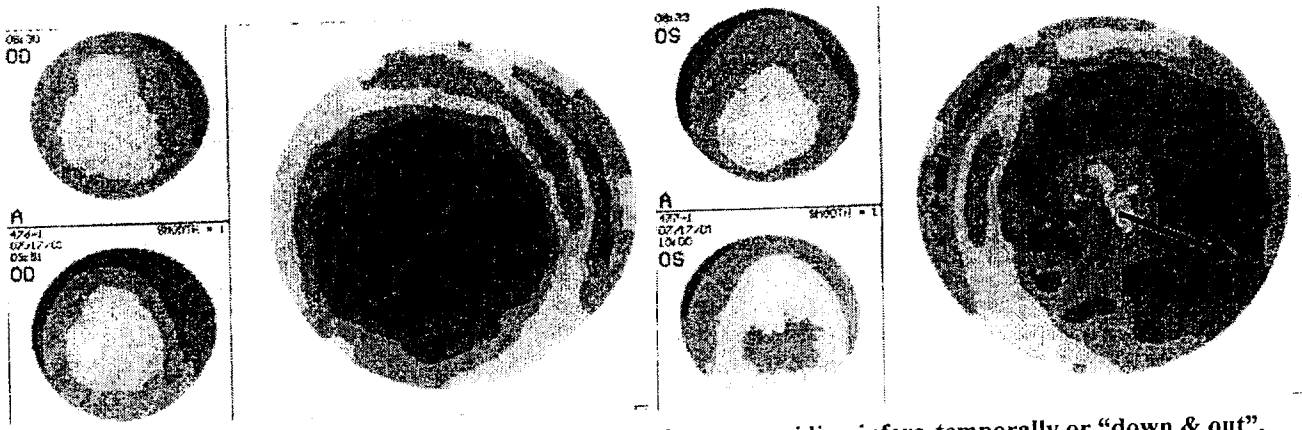


The lens in the right eye is decentered slightly superiorly, whereas the left lens not only rides high, but slightly nasally.

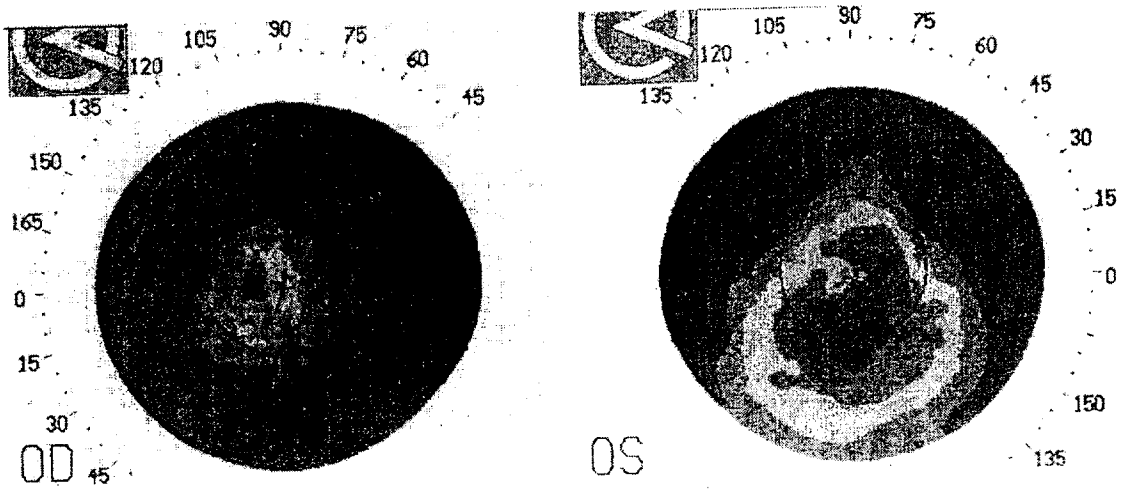
101



The lens are riding low and nasally decentered.

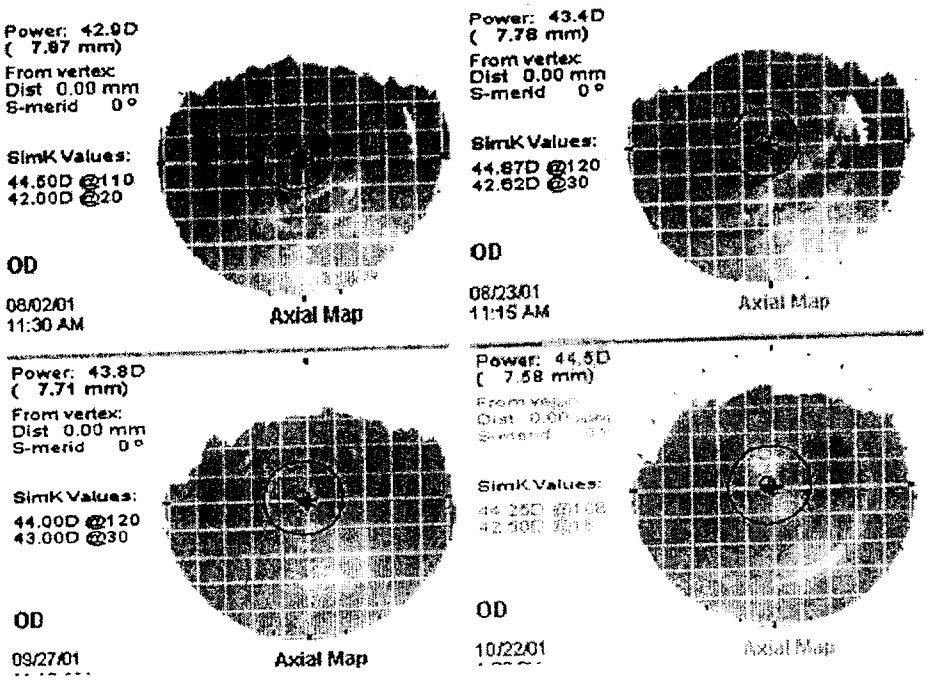


These topography "difference maps" confirm that lenses are riding infero-temporally or "down & out".



The right topography map confirms a low riding lens that is slightly temporal or "down & out". The left map appearance shows this lens is primarily low riding. Both topographies show "central islands" or untreated areas beneath the retainer lenses. Central islands often result from the lens sag been too deep; they may also occur in a well-centered lens or a high riding lens (with the steep zones centered or superiorly located, respectively).

A decentered lens only makes the corneal topography more misshapen if lens parameters remain unchanged (top photos). After increasing the RZD to achieve better centration, it may take months for the cornea to right itself (bottom photos). It is prudent to change lens parameters immediately to eliminate this form of corneal distortion. Do not expect a decentered lens to get better on it's own accord.



103

LZA Assessment Using "Heel Up" and "Heel Down" Concept

Significant edge lift may be seen when the LZA has too low an angle and will present with a "sealed off" periphery when the LZA is too steep.

Other Fitting & Problem Solving Concepts

What to do for "Under Treatment"

1) **If,**
Centered (confirmed with topography, if available)
Treatment zone is round and 5+mm in diameter
Adequate edge lift
PLANO over-refract on the lenses
No induced astigmatism in the MR

and	**then**
Have - 0.50 residual myopia	flatten base curve by 0.50D to 0.75 D
Have - 1.00 residual myopia	flatten base curve by 0.75D to 1.00D
Have - 1.50 residual myopia	reduce LZA 1 degree

2) **If,**
Centered (confirmed with topography, if available)
Treatment zone is round and 5+mm in diameter
Lack edge lift
PLANO over-refract on the lenses
No induced astigmatism in the MR

and	**then**
Have - 1.00 or less residual myopia	reduce LZA 1 degree, and increase BC by no more than 0.50D
Have - 1.50 residual myopia	reduce LZA by 1 degree

3) **If,**
Centered (confirmed with topography, if available)
Treatment zone is round and 5+mm in diameter
Adequate Edge Lift

101

PLANO over-refract on the lenses
No induced astigmatism in the MR,
but have UNCORRECTED residual cylinder power

and
Myopia is fully treated
-or-
Have - 1.00 or less residual myopia
-or-
Have - 1.50 residual myopia

then

Call your Paragon Clinical Specialist; either the LZA, RZD, BC will need to be reduced/flattened or a combination of these processes to reduce sag will be necessary.

What to do for "Over Treatment"

If,

Centered (confirmed with topography, if available)
Treatment zone is round and 5+mm in diameter
Adequate edge lift
PLANO over-refract on the lenses
No induced astigmatism in the MR

and
Spherical power is over-corrected

then
increase the sag by steepening BC or the RZD using a 1:1 relationship per diopter in BC, or approximately 25 microns in RZD per 1.50 diopters

What to do if "Cylinder over-refraction" on the lenses

1) First, ascertain if lens base curve is warped

2) **If,**

No warpage present
Lenses are centered (confirmed with topography, if available)

then

source is lenticular astigmatism

Concerning Lens Appearance

If,

The Lens **Sag Is Too Great** (deep)

the lens will
ride low
undertreat
seal off peripherally
be difficult to remove
ride nasally (if significantly too great/deep)
have Z-axis tilt (if significantly too great/deep)

If,

The Lens **Sag Is Too Little** (shallow)

the lens will
ride high
ride temporally
have Z-axis tilt (if significantly too great/deep)
create secondary corneal SPK
have significant edge lift

10E

Approximate Adjustments in "Sag"

The RZD is adjustable in 25 micron steps.

Base curve changes of 0.50 D represent approximately 7 micron changes.

An LZA reduction of 1 degree and an increase in RZD by 25 microns represent "Relative Sag," and vice versa. Therefore, changes in RZD and LZA in opposite directions are considered a 1:1 relationship.

Fitting Option II

24-Lens Diagnostic Set – Calculation Method

The 24-lens diagnostic set with manual computation forms allows for final prescription determination using clinical data and diagnostic lens evaluation. The fitting set requires calculation based on the following mathematical foundation.

- Manifest refraction sphere in minus cylinder form is adjusted for 12 mm vertex distance.
- Base curve radius is based on attempted treatment plus 0.50 D taken from the pretreatment flat K value.
- Pretreatment clearance at tangential touch diameter is 6 microns per diopter of attempted treatment.
- RZD is the difference in sagittal depth of the lens that "Just Lands" having an LZA of -34 degrees and the depth of the prescribed base curve at a chord of 6 mm.
- RZD is then adjusted an average of 18 microns for each 1 degree of LZA variance from -34 degrees.
- OAD is 90% HVID, rounded to the nearest 0.5 mm.
- Base curve is rounded to nearest 0.1 mm.
- RZD is rounded to nearest 25 microns.

Fitting Step 1

Enter the following clinical data into the computation forms (Worksheet).

1. Flat keratometry measurement in diopters
2. Manifest refraction sphere in minus cylinder form
3. Target sphere in diopters (emmetropia = 0)
4. Measured HVID in millimeters

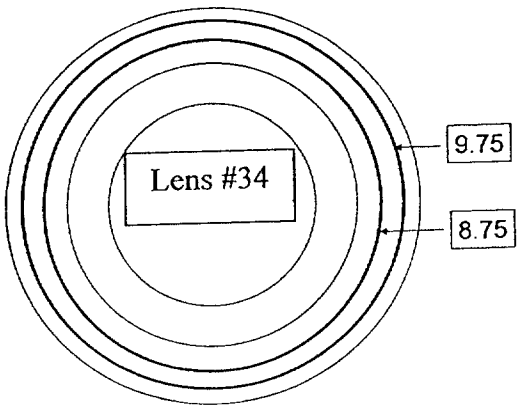
Compute the:

1. Base curve to order (Worksheet Step 1)
2. Power to order (Worksheet Step 10)
3. Overall diameter to order (Worksheet Step 4)

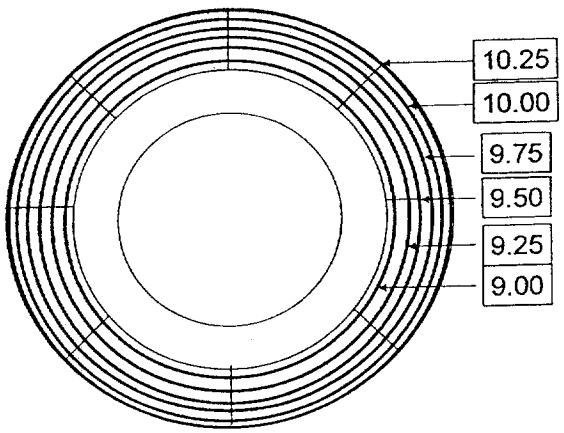
10k

Fitting Step 2

Place #34 diagnostic lens with "observation rings" and observe fluorescein pattern at the Landing Zone Angle to determine the TTD (Tangent Touch Diameter).



Observation Rings at 8.75 mm and 9.75mm

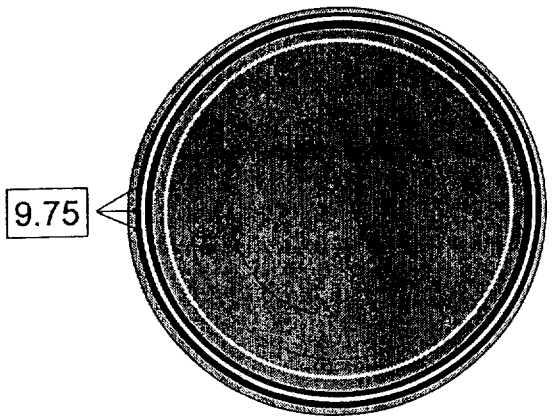


10

Fluorescein pattern with possible Tangent Touch Diameters

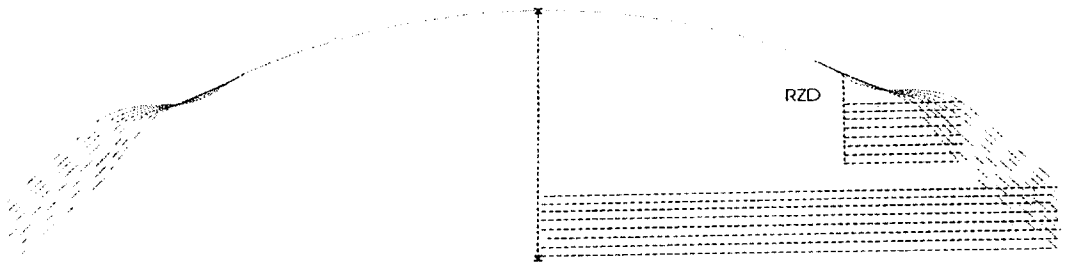
Enter numerical value of TTD (Tangent Touch Diameter) in millimeters into the worksheet.

Example: Utilizing Lens #34; the midpoint of the tangent bearing width in the fluorescein pattern in the Landing Zone is the Tangent Touch Diameter. If the mid-point tangent touch pattern occurs at the 9.75 "observation ring", the diagnostic lens is said to have a Tangent Touch Diameter of 9.75.
This value is entered (Worksheet Step 2) for computation of the correct LZA.



Fitting Step 3

Place lenses from 24 sagittal depth series until determining which number of the 24 lens sagittal depth series "Just Lands".



Note: Lens #24 has the deepest sagittal depth; Lens #1 has the shallowest.

Fitting Step 4

Enter the Lens # of the sagittal depth diagnostic series that "Just Lands" at Worksheet Step 3D.

Note: A numbered sagittal depth diagnostic lens is said to have "Just Landed" when the fluorescein pattern indicates an area of central bearing (3-5mm) with a simultaneous light or "feather touch" of bearing in the lens periphery.

Fitting Step 5

Perform the computations as described on the Worksheet; complete Steps 5, 6, 7, 8 and 9.

A complete lens order includes:

- BCR - Base curve radius
- Lens power
- OAD - Overall diameter
- RZD – Return Zone Depth
- LZA - Landing Zone Angle

Note: The following variables are fixed.

- OZD – Optic zone diameter (6.0 mm)
- Lens thickness – 0.15 for +0.50
- RZW – Return Zone Width (1.0 mm)
- Edge lift system – controlled for each LZA to create uniform edge

Evaluation Of Lenses

The use of the lens prescribing system should result in a lens having a base curve that provides the desired post treatment keratometry target. This lens will also have a Return Zone Depth that will return the lens toward the cornea with enough clearance to allow the corneal apex to retreat posteriorly. The Return Zone clearance will allow for displacement of corneal volume and continued flattening through the optic zone region.

Initially the fluorescein pattern should demonstrate apical bearing over 3 to 5 mm surrounded by pooling under the return curve and initial portion of the Landing Zone. This should be surrounded by an area of tangency without heavy touch or bearing.

1. The absence of apical touch is problematic. This may be the result of the following:

   - Error in calculating the base curve.
   - Diagnostic lens error [lens not to package specification].
   - Return Zone too deep resulting in Return Zone junction bridging [outer Return Zone bearing that lifts the optic zone off the cornea].
   - Landing Zone angle too large resulting in Landing Zone bridging [Landing Zone bearing that lifts the optic zone off the cornea].

   In the case of Return Zone or Landing Zone bridging, the fluorescein pattern will demonstrate a black circle of touch. For Return Zone junction bridging, the black circle will be at the outer junction of the Return Zone. For Landing Zone bridging, the black circle will be further out toward the lens edge. If the Return Zone is too deep AND the Landing Zone Angle is also too deep, the pattern will appear like Landing Zone bridging. To differentiate, first place a diagnostic lens having a Return Zone that is less deep. If the pattern still appears like Landing Zone bridging, the Landing Zone Angle must be decreased

   Keep in mind that cases of low target myopia reduction and moderate myopia reduction with high eccentricity may NOT require Paragon CRT™ contact lenses. In these cases, even the shallowest Return Zone may cause Return Zone bridging. In this event, consider a conventional large diameter tricurve RGP lens design.

2. Return Zone too shallow

   If the Return Zone depth is too shallow, the lens will fail to approach the cornea outside the optic zone. The result will be a lens that teeters or tilts on the apex or decenters. When nudged to center, the lens pattern will demonstrate excessive clearance under the Return Zone and much of the Landing Zone. Bubbles may form under the lens and the lens may easily move off the cornea.

3. Decentration and excessive clearance

Remove the lens and recheck the following:

- Base curve and Return Zone depth determination.
- Diagnostic lens error [lens not to package specification].

Note: All Paragon CRT™ and Paragon CRT™ 100 lenses are laser-marked in the Return Zone with a five place designation. The first two numbers correspond to the base curve, the second two denote the RZD and the fifth [letter] indicates the LZA.

The laser mark should be inspected when lenses do not demonstrate expected patterns.

If the determination and lens measurements are correct, select a lens with a greater Return Zone Depth. After placing the lens, the clearance and decentration should be reduced. If the Return Zone clearance is appropriate but the lens continues to gain in clearance toward the edge, the Landing Zone Angle is too small and the final lens order should reflect the need for a larger angle.

When initially placed and allowed to equilibrate, the well-fit lens will center and provide for a fluorescein pattern that demonstrates central bearing, paracentral clearance and peripheral alignment. After treatment, the fluorescein pattern will appear to be aligned through all zones of the lens with a low degree of paracentral clearance.

The initial pattern of a poorly fit lens may demonstrate any of the following characteristics.

- Poor centration
- Absence of central bearing
- Absence of paracentral clearance
- Excessive paracentral clearance with bubbles in the Return Zone
- Heavy bearing [black arc] at junction of the Return Zone and peripheral Landing Zone
- Heavy bearing through the peripheral Landing Zone
- Excessive clearance in the peripheral Landing Zone

The presence of any of the poorly fit patterns is followed by failure to obtain optimum treatment. A well-fit lens pattern must be achieved through diagnostic lens fitting prior to lens ordering.

Manual Prescribing System Worksheet

		OD		OS
Step 1	**Calculate the Base Curve Radius**			
	A. Flat Keratometry Value in Diopters	D		D
	B. Subtract Diopters Attempted Correction after vertex adjustment (positive value)	- D		- D
	C. Subtract extra 0.50 D	- 0.50 D		- 0.50 D
	= Base Curve Radius in Diopters	D		D
	D. Look up value in millimeters and round to nearest 0.10 mm	mm	BCR = Rx	mm
Step 2	**Determine the Tangential Touch Diameter** Place lenses #33 Estimate TTD (midpoint of zone of tangency)	mm		mm
Step 3	**Find the Lens ID # that "Just Lands" using fluorescein** A. Look up Lens ID # that corresponds to BCR from step one B. Place these lenses on corresponding eyes and observe "Clearance" or "Just Landed" or "Excessive Landing"	# C / J / E		# C / J / E
	If lens in Step 3 demonstrates Clearance insert 2 lens # higher If lens in Step 3 is Excessively Landed apply 2 lens # lower	# C / J / E		# C / J / E
	C. Repeat on each eye until Lens # of lens that "Just Landed" is known	# C / J / E		# C / J / E
	D. Circle lens # of diagnostic lens that just lands for use in Step 5	# C / J / E		# C / J / E
Step 4	**Determine ideal Over-All Diameter (90% HVID) OAD: Small = 10.0; Average 10.5 ; Large 11.0**	mm	OAD Rx	mm
Step 5	**Micron adjustment for variance of corneal height from the mean** A. Look up sag of Lens ID # that "just landed" in Steps 3 or 4 B. Look up sag for calculated BCR with mean RZD and 33 degree LZA C. Amount "just Landed" sag is greater (+) or less (-) than mean BCR (sign sensitive)	Microns		Microns
Step 6	**Look up LZA using TTD from Step 2 and OAD from Step 5** Look up LZA required to put TTD midway between midpoint and edge	Degrees	LZA Rx	Degrees
Step 7	**Look up RZD adjustment for Rx LZA variance from 33 degrees** Look up microns of adjustment for change to new LZA (sign sensitive)	Microns		Microns
Step 8	**Micron adjustment for required clearance for attempted treatment** Multiply attempted treatment from Step 1 X 6 microns (positive value)	Microns		Microns
Step 9	**Determine final RZD using values from Steps 6, 8 and 9** Mean RZD value	560 Microns	a	560 Microns
	Adjustment from Step 6 (sign sensitive)	Microns	b	Microns
	Adjustment from Step 8 (sign sensitive)	Microns	c	Microns
	Subtract Adjustment from Step 9	- Microns	d	- Microns
	Combine a,b,c & d; **round to nearest 25 micron** for RZD prescription	Microns	RZD Rx	Microns
Step 10	**Calculate Lens Power (using extra 0.50 D adjustment to base curve)** Add +0.50 to attempted post treatment refractive sphere	D	Power Rx	D

Step 1 B: Look up table for vertex adjusted amount of attempted correction.
Enter as positive value in worksheet

Attempted Correction "S" in Diopters	12 mm Vertex Adjusted Correction (D)
-3.50	-3.38
-.375	-3.63
-4.00	-3.88
-4.25	-4.00
-4.50	-4.25
-4.75	-4.50
-5.00	-4.75
-5.25	-5.00
-5.50	-5.13
-5.75	-5.38
-6.00	-5.63
-6.25	-5.88
-6.50	-6.00

Step 1 D: Look up table for conversion of Base Curve Radius in Diopters to BCR to nearest 0.10 mm

Calculated Base Curve Radius in Diopters	BCR Rounded to Nearest 0.10 mm
32.63	10.30
32.75	10.30
32.88	10.30
33.00	10.20
33.13	10.20
33.25	10.10
33.38	10.10
33.50	10.10
33.63	10.00
33.75	10.00
33.88	10.00
34.00	9.90
34.13	9.90
34.25	9.90
34.38	9.80
34.50	9.80
34.63	9.70
34.75	9.70
34.88	9.70
35.00	9.60
35.13	9.60
35.25	9.60
35.38	9.50
35.50	9.50
35.63	9.50
35.75	9.40
35.88	9.40
36.00	9.40
36.13	9.30
36.25	9.30
36.38	9.30
36.50	9.20
36.63	9.20
36.75	9.20
36.88	9.10
37.00	9.10
37.13	9.10
37.25	9.10
37.38	9.00
37.50	9.00
37.63	9.00
37.75	8.90
37.88	8.90
38.00	8.90
38.13	8.80
38.25	8.80
38.38	8.80
38.50	8.80
38.63	8.70
38.75	8.70
38.88	8.70
39.00	8.70
39.13	8.60
39.25	8.60
39.38	8.60
39.50	8.50
39.63	8.50
39.75	8.50
39.88	8.50
40.00	8.40
40.13	8.40
40.25	8.40
40.38	8.40
40.50	8.30
40.63	8.30
40.75	8.30
40.88	8.30
41.00	8.20
41.13	8.20
41.25	8.20
41.38	8.20
41.50	8.10
41.63	8.10
41.75	8.10
41.88	8.10
42.00	8.00
42.13	8.00
42.25	8.00
42.38	8.00
42.50	7.90
42.63	7.90
42.75	7.90
42.88	7.90
43.00	7.80
43.13	7.80
43.25	7.80
43.38	7.80
43.50	7.80
43.63	7.70
43.75	7.70
43.88	7.70
44.00	7.70
44.13	7.60
44.25	7.60
44.38	7.60
44.50	7.60
44.63	7.60
44.75	7.50
44.88	7.50
45.00	7.50
45.13	7.50
45.25	7.50
45.38	7.40
45.50	7.40
45.63	7.40
45.75	7.40
45.88	7.40
46.00	7.30
46.13	7.30
46.25	7.30
46.38	7.30
46.50	7.30
46.63	7.20
46.75	7.20
46.88	7.20
47.00	7.20

112

Step 3A & 5 A and B: Look up table for determining starting lens #; Sagittal depth difference at a 9.75 mm chord between calculated Base Curve Radius with Mean RZD and 33 degree LZA and System 24 lens of known sagittal depth

Calculated Base Curve Radius	Sag @ 9.75 mm of BCR with Mean RZD and 33 Angle	Sag @ 9.75 mm of most closely matching fitting set lens	Lens # of most closely matching fitting set lens	Laser Mark of most closely matching fitting set lens
7.30	1.715	1.719	19	84560I
7.40	1.706	1.709	18	8660I
7.50	1.696	1.694	17	84558I
7.60	1.687	1.684	16	8658I
7.70	1.679	1.684	16	8658I
7.80	1.670	1.669	15	84555I
7.90	1.662	1.659	14	8655I
8.00	1.654	1.659	14	8655I
8.10	1.646	1.644	13	84553I
8.20	1.639	1.644	13	84553I
8.30	1.631	1.634	12	8653I
8.40	1.624	1.619	11	84550I
8.50	1.617	1.619	11	84550I
8.60	1.610	1.609	10	8650I
8.70	1.604	1.609	10	8650I
8.80	1.597	1.594	9	84548I
8.90	1.591	1.594	9	84548I
9.00	1.585	1.584	8	8648I
9.10	1.579	1.584	8	8648I
9.20	1.573	1.569	7	84545I
9.30	1.567	1.569	7	84545I
9.40	1.562	1.559	6	8645I
9.50	1.556	1.559	6	8645I
9.60	1.551	1.544	5	84543I
9.70	1.546	1.544	5	84543I
9.80	1.541	1.544	5	84543I
9.90	1.536	1.534	4	8643I
10.00	1.531	1.534	4	8643I
10.10	1.526	1.519	3	84540I
10.20	1.521	1.519	3	84540I
10.30	1.517	1.519	3	84540I

Step 6 and 7: Look up table for determining proper Landing Zone Angle from observed Tangent Touch Diameter and required microns of Return Zone Depth adjustment.

	If HMD dictates OAD of 10.0 and target Tangential Touch Diameter (TTD) is ~9.00 mm										
If -34 has TTD @	8.2	8.5	8.7	9	9.2	9.5	9.7	10			
choose new LZA of	-37	-36	-35	-34	-33	-32	-31	-30			
adjust RZD by	-0.053	-0.033	-0.025	-0.014	0.000	0.017	0.036	0.058			
to give new TTD @	9.33	9.17	9.21	9.24	9.25	9.24	9.22	9.18			
	If HMD dictates OAD of 10.5 and target Tangential Touch Diameter (TTD) is ~9.50 mm										
If -34 has TTD @	8.2	8.5	8.7	9	9.2	9.5	9.7	10	10.2	10.5	
choose new LZA of	-40	-39	-37	-36	-35	-34	-33	-32	-31	-30	
adjust RZD by	-0.070	-0.073	-0.064	-0.053	-0.038	-0.020	0.000	0.023	0.048	0.072	
to give new TTD @	9.44	9.59	9.67	9.71	9.74	9.75	9.75	9.73	9.69	9.55	
	If HMD dictates OAD of 11 and target Tangential Touch Diameter (TTD) is ~10.00 mm										
If -34 has TTD @					9.2	9.5	9.7	10	10.2	10.5	10.7
choose new LZA of					-37	-36	-35	-34	-33	-32	-31
adjust RZD by					-0.091	-0.073	-0.051	-0.027	0.000	0.029	0.060
to give new TTD @					10.22	10.25	10.27	10.27	10.25	10.22	10.17

UNDERSTANDING POOR FIT DYNAMICS

1. Poor Centration

Poor centration can result from insufficient fluid forces relative to lid interaction or gravity. If the lens is nudged to center and it demonstrates ideal central bearing, paracentral clearance, and peripheral tangency, the overall diameter is too small and centration should be achieved by increasing overall diameter only.

If the pattern is ideal in the central and paracentral zones but the landing zone exhibits clearance, the angle of the peripheral zone must be increased along with a possible diameter increase.

Poor centration can result from too much sagittal depth in the lens as well. If the poor centration is accompanied by either lack of central bearing, excessive return zone depth [bubble formation] or excessive bearing at the Return Zone – Landing Zone junction (junction two), the Return Zone Depth should be reduced first to see if centration is achieved.

2. Absence Of Central Bearing

A lens may fail to demonstrate central bearing for two reasons. First, the base curve selected may simply be wrong. Recheck the keratometry or corneal topography to be sure the lens selected is flatter than the corneal apex. If the base curve has been properly selected, the cause is most always excessive sagittal depth with resultant "bridging". If the Return Zone Depth is too great, the lens will gain in sagittal depth relative to the same chord diameter of the cornea. Even a lens that has a base curve that is significantly flatter than K may vault the cornea. In this case, the fluorescein pattern should demonstrate an arc bearing outside the Return Zone.

This arc bearing is the foundation of the "Lens Bridge". The lens designed as flatter than k with a Return Zone that is too deep or too wide will span over the corneal apex instead of bearing on it.

The solution for this problem is to decrease the RZD. The lens will then be free to touch first in the central bearing zone instead of at the outside of the Return Zone.

In cases of high pre treatment corneal eccentricity it is possible for the Landing Zone Angle to also be too large in combination with the Return Zone Depth. In this case, the "bridging" starts with bearing toward the edge of the lens or the most peripheral portion of the Landing Zone. Decreasing the angle of the Landing Zone will allow the lens to increase its central bearing.

3. Absence Of Paracentral Clearance

The use of a yellow Wrattan filter is recommended to assist in detecting tear film thickness variances under the lens with fluorescein.

If a lens exhibits a uniform tear film when initially placed and the paracentral clearance zone is not apparent, you must first recheck the lens to determine that it has a proper design . Naked eye inspection of the ocular surface using the reflection of a single fluorescent lamp tube should facilitate determination of sigmoid geometry in the paracentral zone that is steeper than the base curve. This general inspection should reveal breaks in the lamp that correspond to the changes in geometry. You may also use the corneal topographer to capture and process an image of the base curve of the lens. Note: All Paragon CRT™ and Paragon CRT™ 100 lenses have a five-place laser mark in the Return Zone.

A lens having too much overall sagittal depth may seal off and prevent fluorescein from migrating under the lens. The result is a pattern that is uniform and without color. The lens can be nudged or partially lifted to allow the fluorescein containing tear film to travel under the lens. In this case, the pattern will significantly change and demonstrate excessive "bridging".

Experience will result in increased judgment of the proper ratio of central bearing and paracentral clearance for a given amount of refractive change. The greater the attempted dioptric change, the greater the central bearing and the greater the paracentral clearance. For that reason, a one diopter-attempted change will not demonstrate deep or wide paracentral clearance.

4. Excessive Paracentral Clearance With Bubbles In The Return Zone

A lens with too much clearance at junction one before returning to the cornea may contain air bubbles in the optic zone and Return Zone. Check the base curve to determine it is correct for the attempted treatment. If the base curve is correct and the proper Return Zone Depth is in place and the peripheral tangency and edge lift appear good, the optic zone should be reduced to decrease the junction one elevation from the cornea. This is expected in some cases above 5.00 diopters of target treatment. In some cases, bubbles are reduced by reducing the RZD by 25 microns or the LZA by 1 degree.

5. Heavy Bearing [Black Arc] At Junction Of Return Zone And Landing Zone

If the optic zone bearing and Landing Zone tangency are good, the Return Zone is too deep and must either be reduced in width or decreased in depth. An increase in the Landing Zone Angle will also move the midpoint of the tangency out from the junction and toward the lens edge.

6. Heavy Bearing Through The Landing Zone

Once again, verify that the base curve is correct and the Return Zone is proper for the attempted treatment. If the bearing is less than full seal off but the fluorescein pattern demonstrates a uniform dark bearing instead of a light tear film clearance decrease the Landing Zone Angle one level. If the Landing Zone actually approaches seal off, decrease the RZD in conjunction with the LZA.

7. Excessive Clearance In Landing Zone

This problem is often associated with poor centration. To study the fluorescein pattern, always nudge the lens to center, while minimizing any tilting of the lens. If the lens demonstrates proper central bearing and junction two clearance but the Landing Zone progresses to too much edge lift or excessive clearance, increase the Landing Zone Angle.

PROBLEM SOLVING TABLE

Problem	Possible Cause	Solution
Apical clearance	• bridging due to excessive sagittal depth	• Decrease Return Zone Depth • Decrease Landing Zone Angle •
Excess central bearing, lack of good centration	• base curve too flat • shallow Return Zone Depth • Landing Zone Angle too small	• Increase Return Zone Depth • Increase Landing Zone Angle
Poor lateral centration	• inadequate sagittal depth • inadequate lens diameter	• Increase depth of Return Zone • Increase Landing Zone Angle • Increase overall diameter*
Superficial punctate staining	• sag of lens inadequate • ocular lens surface has become soiled	• Increase depth of Return Zone • Increase Landing Zone Angle • Clean or replace lens
Lack of movement	• sag of lens excessive	• Decrease Return Zone Depth • Decrease Landing Zone Angle • Decrease overall diameter*
Excessive LZ clearance	• junction two clearance is excessive • low corneal eccentricity	• Increase Return Zone Depth • Increase Landing Zone Angle
Over-treatment	• excessive corneal reshaping	• Steepen base curve of optic zone
Under-treatment without apical pooling	• base curve too steep • poor lens centration	• Flatten base curve of optic zone and increase the Return Zone Depth as needed • Improve centration increase Landing Zone Angle
Under-treatment with apical pooling	• bridging	• RZ bridging-decrease Return Zone Depth • LZ bridging -decrease the Landing Zone Angle
Tight lens or no movement	• Return Zone too deep • diameter too large	• Decrease Return Zone Depth • Reduce diameter
Loose lens	• Return Zone too shallow • Landing Zone too small • diameter too small	• Increase Return Zone Depth • Increase Landing Zone Angle • Increase diameter
High-riding lens	• Landing Zone Angle too small • diameter too small	• Increase Landing Zone Angle • Increase diameter
Low-riding lens (without bridging)	• Landing Zone too shallow • diameter too small	• Increase Landing Zone Angle • Increase diameter*
Flare, glare or ghosts	• Return Zone bridging • poor centration	• Decrease Return Zone Depth • Increase diameter*
Fogging and scratchy lens	• dirty lens • improper care & handling of lenses • oily eye make-up removers	• See "Lens Care"
Increase in corneal astigmatism	• poor centration • diameter too small • Return Zone too shallow	• Improve centration • Increase diameter* • Increase Return Zone Depth
Poor VA with lenses	• poor centration • power error	• Improve centration • Check over-refraction/lens power
Poor VA without lenses	• poor centration • irregular corneal astigmatism • bridging	• Increase LZA and/or OAD • Improve centration • See under-treatment solutions

*common adjustment, increase 0.5 mm in diameter up to 12.0 or 0.5 mm less than corneal diameter

FOLLOW-UP CARE

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

2. On the first morning following overnight wear, with lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the cornea flattens rapidly there will be a larger area of central touch and the pooling at the lens transition will be reduced. The lens will usually show reduced movement.

3. A lens with excessive movement should be replaced with another that is larger in diameter and approaches the corneal diameter less 0.5 to 1.0 mm. Landing Zone Angle should be reevaluated to determine possible need for larger LZA.

4. If the cornea shows no flattening, this may be due to a base curve that is not flat enough or a Return Zone that is too deep, resulting in "bridging". Bridging is caused by the outer junction of the Return Zone having a heavy touch. The result of the touch is the lifting of the base curve off the cornea. When the base curve is lifted off the central cornea, it will not flatten the cornea, even if the base curve is significantly flatter than the cornea it is covering. If the base curve has been selected to be flatter than the cornea equivalent to the attempted reduction in myopia, the failure to flatten most often resides in a Return Zone that is too deep. In this case, the Return Zone Depth should be decreased until the fluorescein pattern demonstrates a proper central bearing of 3.0 to 5.0 mm.

5. After lens removal, conduct a thorough biomicroscopy examination to detect the following:

   - The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.

   - The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of a reaction to solution preservatives, excessive lens wear, and/or a poorly fitted lens.

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 - Day 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 the Paragon CRT™ and Paragon CRT™ 100 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 CRT™ or Paragon CRT™ 100 contact lenses for overnight 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.

HANDLING OF LENSES

Standard procedures for rigid gas permeable lenses may be used.

CAUTION: Paragon CRT™ and Paragon CRT™ 100 Contact Lenses for Corneal Refractive Therapy are shipped to the practitioner nonsterile. Clean and condition lenses prior to use.

PATIENT LENS CARE DIRECTIONS

Please see Package Insert of lens care product.

VERTEX DISTANCE AND KERATOMETRY CONVERSION CHARTS

Standard charts may be used.

HOW SUPPLIED

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

Each Paragon CRT™ and Paragon CRT™ 100 lens is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in Unique-pH™ Multi-Purpose Solution. This solution contains hydroxypropyl guar, a unique wetting and conditioning polymer system, polyethylene glycol, Tetronic*, boric acid, propylene glycol; and, is preserved with POLYQUAD® (polyquarternium-1) 0.0011% and edetate disodium 0.01%. The case, packing slip or invoice is marked with the central base curve radius, diameter,

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 unpreserved saline prior to cleaning, disinfecting and dispensing.

* Registered Trademark of BASF corp.
Unique-pH™ is a Trademark of Alcon Laboratories, Inc.

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). If the lens is stored for longer periods of time, it should be cleaned and disinfected with a recommended product (see product list in the Lens Care Directions section), 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
947 E. Impala Avenue
Mesa, Arizona 85204-6619

1-800-528-8279
1-480-892-7602
1-480-926-7369 FAX

(Package Insert enclosed)

(print date)

PROFESSIONAL FITTING AND INFORMATION GUIDE

Paragon Quadra RG™

Manufactured in
Paragon HDS® (paflufocon B)

or

Paragon Quadra RG™ 100

Manufactured in
Paragon HDS® IOO (paflufocon D)

RIGID GAS PERMEABLE CONTACT LENSES FOR CONTACT LENS CORNEAL REFRACTIVE THERAPY

OVERNIGHT WEAR

TABLE OF CONTENTS

INTRODUCTION

Paragon Quadra RG™ and Paragon Quadra RG™ 100 Contact Lenses for Corneal Refractive Therapy produce a temporary reduction of myopia by reversibly altering the curvature of the cornea. The Paragon Quadra RG™ and Quadra RG™ 100 contact lenses are manufactured from Paragon HDS® and Paragon HDS® 100 respectively. A slight reduction of the curvature of the cornea can reduce the excessive focusing power of the myopic eye. If the amount of corneal reshaping is precisely controlled as is the objective of Quadra RG™ lens designs, it is possible to bring the eye into correct focus and completely compensate for myopia. After the contact lens is removed, the cornea retains its altered shape for all or most of one's waking hours. The lens is designed to be worn overnight with removal during following day. The Paragon Quadra RG™ and Paragon Quadra RG™ 100 lenses must be worn at night on a regular schedule to maintain the corneal reshaping, or the pretreatment myopia will return.

PRODUCT DESCRIPTION

The Paragon Quadra RG™ and Quadra RG™ 100 four zone reverse geometry designs are manufactured in Paragon HDS® (paflufocon B) and Paragon HDS® 100 (paflufocon D) rigid gas permeable contact lens materials. The designs have posterior surfaces 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 Quadra RG™ and Paragon Quadra RG™ 100 Contact Lenses for Corneal Refractive Therapy are to be worn overnight with removal during all or part of each following day. Both materials are 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 Refractive Therapy are available as lathe cut firm contact lenses with blue and green tints. The blue tinted lens contains D&C Green No. 6. The green lens contains D&C Green No. 6 and Perox Yellow No.9.

Detailed Description

Generally the central base curve is chosen to be flatter than the curvature of the central cornea by an amount such that if the cornea were to take on this lens curvature a significant reduction in myopia would be expected. The lens is fitted to allow this zone to contact the central corneal apex. Until such time as the cornea has taken on the curvature of this zone of the lens, it is expected that this zone will gradually diverge from the corneal curvature, thus rising away from it with a maximum deviation at the edge of the zone. The zone is characterized by its diameter, radius and eccentricity.

The first zone peripheral to the central base curve, the Reverse Zone, has a spherical or slightly aspherical shape with a curvature steeper than the central base curve. This is the "reverse" of the arrangement found in lenses not designed to alter corneal curvature. This zone is characterized by the increased diopteric power it possesses relative to the central zone and the width of the zone.

The third element, generally referred to as an Alignment Zone, can be described as spherical or as a conic section with a curvature nearly that of the underlying cornea. It is concentric to the Reverse Zone. This element is intended to parallel the cornea, initiating contact on fitting and maintaining nearly constant contact during treatment over the width of the zone. The contact with the peripheral cornea is intended to exert compressive force on and to move the peripheral corneal epithelium centrally to enhance the effects of the central zone in changing corneal shape. Since the Alignment Zone parallels the underlying cornea, which is typically flattening

in this region a continuation of the curve would likely ultimately impinge on the cornea creating a region of excessive bearing. This factor leads to the need for an additional peripheral curve to give "edge lift". Fluid forces arising from the approximation of Alignment Zone and cornea participate with other factors in stabilizing the lens orientation on the eye. The Alignment Zone is characterized by its radius of curvature and by its chord diameter; both parameters are selected by the fitter.

The fourth zone is the peripheral curve, this zone is common to nearly all historic RGP designs regardless of their intended mode of action is still concave toward the cornea but generally significantly flatter than the curvature of all zones it surrounds and the underlying cornea. It is designed to lift the lens surface away from the cornea and create a region of tear pooling promoting tear flow upon lens movement. This zone is characterized typically by its radius and width.

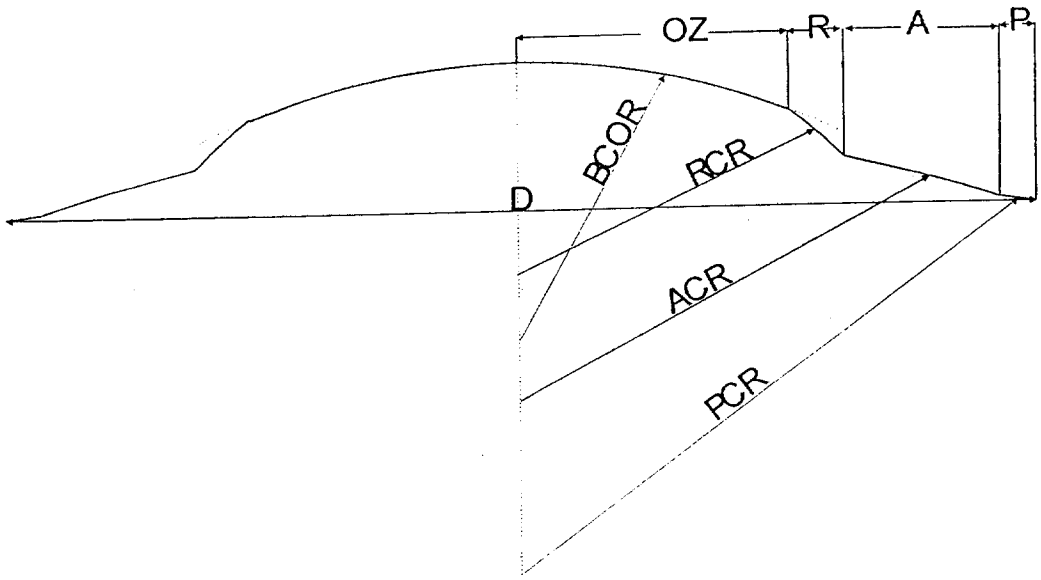
The last and most peripheral element, the edge terminus, deviates from the Alignment Zone and curves away from the underlying cornea to merge with the anterior surface thereby forming the edge of the lens. The edge has a separate contour which is created by grinding and polishing the edge but its shape is typically dictated by the nature of the processes and lens edge thickness. When the shape is characterized it is done by attempting to describing the intended location of the apex of the edge contour relative to the midline between the anterior and posterior surfaces.

Paragon Quadra RG™ and Paragon Quadra RG™ 100contact lenses are used to temporarily reshape the cornea to change its refractive power with a resultant reduction in the pre-treatment refractive error. Corneal tissue is redistributed without significant alteration of its physiology. The change in shape is the result of gentle mechanical pressure from the flattened central zone of the lens augmented by the availability of unoccupied volume beneath the Reverse and Alignment Zones of the lens and concomitant peripheral pressure from the Alignment Zone. After wearing of the lens, the cornea typically demonstrates an increased radius of curvature in the central area and a decreased radius of curvature in the paracentral area allowed by the clearance within the outer portion of the optic zone and the Reverse Zone of the lens.

Although rarely required, the anterior central curve is selected to provide any necessary optical power to correct residual refractive error not corrected by the optical and mechanical effect of the posterior base curve and the tear lens formed between it and the cornea. Typically the anterior and posterior surfaces deviate from one another as is dictated the need to maintain lens minimal and maximal thicknesses. Lens thicknesses in the four zones are dependent on lens parameters but attempts are made to maximize oxygen transmission, stability and comfort.

LENS PARAMETERS AVAILABLE (See drawing)

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 Quadra RG™ LENS (paflufocon B)

Refractive Index	1.449 (Nd at 25°C)
Luminous Transmittance+ (Blue)	95%
Wetting Angle (Receding Angle)	14.7°
Specific Gravity	1.16
Hardness (Shore D)	84
Water Content	<1%

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

ATTRIBUTES OF THE PARAGON Quadra RG™ 100 LENS (paflufocon D)

Refractive Index	1.442 (Nd at 25°C)
Luminous Transmittance+ (Green)	95%
Wetting Angle (Receding Angle)	42°
Specific Gravity	1.10
Hardness (Shore D)	79
Water Content	<1%

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

OXYGEN PERMEABILITY - QUADRA RG™ LENS DESIGN****

Material	Power	Oxygen Permeability (Revised Fatt Method*) Dk x 10^{-11}	Oxygen Permeability (ISO Method**) Dk x 10^{-11}	Center Thickness (mm)	Harmonic Mean Thickness*** (mm)	Oxygen Transmissibility (Fatt) Dk/l x 10^{-9}	Oxygen Transmissibility (ISO) Dk/l x 10^{-9}
HDS 100	-2.00	145	100	0.180	0.194	75	52
HDS 100	Plano	145	100	0.200	0.190	76	53
HDS 100	+2.00	145	100	0.240	0.203	71	49
HDS	-2.00	58	40	0.180	0.194	30	21
HDS	Plano	58	40	0.200	0.190	31	21
HDS	+2.00	58	40	0.240	0.203	29	20

* (cm^2/sec) (mL O_2)/ (mL x mm Hg) Revised Method of I. Fatt
** (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.
**** The lens design is the generic 4 curve from Cho, et al. (Optom Vis Sci 2002;79:175-183)

ACTIONS

Paragon Quadra RG™ and Paragon Quadra RG™ 100 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 Quadra RG™ and Paragon Quadra RG™ 100 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. These 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 Quadra RG™ (paflufocon B) and Paragon Quadra RG™ 100 (paflufocon D) 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 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 Refractive Therapy effect of myopia reduction lens wear must be continued on a prescribed wearing 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)

Reference the so entitled section found in the enclosed Package Insert.

WARNINGS

Reference the so entitled section found in the enclosed Package Insert.

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

Reference the so entitled section found in the enclosed Package Insert.

PRECAUTIONS

Reference the so entitled section found in the enclosed Package Insert.

SELECTION OF PATIENTS

Patients are selected who have a demonstrated need and desire for a refractive reduction by contact lens Corneal Refractive Therapy with rigid gas permeable contact lenses and who do not have any of the contraindications for contact lenses previously described. Paragon Quadra RG™ and Paragon Quadra RG™ 100 Contact Lenses for Corneal Refractive Therapy are indicated for myopic patients who desire not to wear vision correction devices during the daytime hours, but still require the ability to see clearly during that time.

Paragon Quadra RG™ and Paragon Quadra RG™ 100 contact lenses for overnight Contact Lens Corneal Refractive Therapy are primarily intended for patients who are within the following parameters.

Refractive Error	-0.5 to – 3.00 diopters with up to –1.50 diopters of astigmatism
Keratometry	37 to 52 diopters
Visual Acuity	20/20 to 20/1000

FITTING CONCEPT

Paragon Quadra RG™ and Paragon Quadra RG™ 100 Contact Lenses for Corneal Refractive Therapy are designed to be fitted so as to flatten the central cornea and thereby reduce myopia. This goal is accomplished by the lens design and the manner in which the lens is fitted.

These contact lenses for Corneal Refractive Therapy have a design known as reverse geometry. This means that the secondary curve on the posterior surface has a radius of curvature that is steeper (shorter radius) than the base curve (central curve). The secondary curve is surrounded by a flatter peripheral curve near the edge (Figure 1). In this way the geometry of the secondary curve is in the opposite relationship to the base curve, as occurs with standard rigid gas permeable contact lenses.

The function of the steep secondary curve in these contact lenses for Corneal Refractive Therapy is to allow the base curve to be fitted flat in relation to the central cornea and still maintain lens stability on the cornea. With a regular contact lens design, that is fitted flat on the cornea, there is only one support point for the contact lens, which occurs at the center of the lens. This lens will tend to rock and decenter on the cornea. With the Paragon Quadra RG™ and Paragon Quadra RG™ 100 Contact Lenses for Corneal Refractive Therapy there is support for the lens at both the central cornea and in the area of the Alignment Curve. This tends to reduce lens rocking and aid in centering.

The most commonly used configuration for the Paragon Quadra RG™ and Paragon Quadra RG™ 100 contact lenses has a secondary curve that is 3.00 diopters steeper (shorter radius) than the base curve. The Alignment Curve is equal to the radius of the flat central corneal meridian as measured by keratometry. The peripheral curve is a standard flatter curve. The secondary curve relationship can be altered to achieve an optimal lens design for each patient. Normally the secondary curve is between 2.00 and 4.00 diopters steeper than the base curve. In some lenses the secondary curve is divided into two curves of nearly equal width. The inner portion of the secondary curve is equivalent to the usual radius value of the Paragon Quadra RG™ or Paragon Quadra RG™ 100 lens and the outer portioned is flattened to provide a smooth transition to the peripheral curve, in the manner of a blend.

Predicting Lens Results

Clinical studies have not established reliable methods to predict which patients will achieve the greatest corneal flattening with these contact lenses for Corneal Refractive Therapy.

Paragon Quadra RG™ and Paragon Quadra RG™ 100 Contact Lenses for Corneal Refractive Therapy may produce a temporary reduction of all or part of a patient's myopia. The amount of reduction will depend on many factors including the amount of myopia, the elastic characteristics of the eye and the way that the contact lenses are fitted. Average amounts of reduction have been established by clinical studies but the reduction for an individual patient may vary significantly from the averages.

CLINICAL STUDY DATA

Reference the so entitled section found in the enclosed Package Insert.

RISK ANALYSIS

There is a small risk involved when any contact lens is worn. It is not expected that Paragon Quadra™ or Paragon Quadra™ 100 contact lenses for orthokeratology will provide a risk that is greater than other rigid gas permeable contact lenses.

The two most common side effects, which occur in rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that these two side effects will also occur in some wearers of Paragon Quadra™ or Paragon Quadra™ 100 contact lenses for orthokeratology. Other side effects, which sometimes occur in all hard contact lens wearers are pain, redness, tearing, irritation, discharge, abrasion of the eye or distortion of vision. These are usually temporary conditions if the contact lenses are removed promptly and professional care is obtained. When overnight orthokeratology lenses dislocate during sleep, transient distorted vision may occur the following morning after removal of the lenses. This distortion may not be immediately corrected with spectacle lenses. The duration of distorted vision would rarely be greater than the duration of the daily visual improvement normally achieved with the lenses.

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

FITTING PARAGON QUADRA RG™ AND PARAGON QUADRA RG™ 100 CONTACT LENSES FOR CORNEAL REFRACTIVE THERAPY

Note: Contact lenses for Corneal Refractive Therapy should be fitted only by a trained and certified contact lens fitter.

Paragon Quadra RG™ and Paragon Quadra RG™ 100 contact lenses for Contact Lens Corneal Refractive Therapy may be fitted using a modification of the standard techniques for rigid gas permeable contact lenses.

1. Prefitting Examination

   A complete refraction and visual health examination should be performed. Pre-fitting patient history and examination are necessary to determine whether a patient is a suitable candidate for Paragon Quadra RG™ or Paragon Quadra RG™ 100 Contact Lenses for Contact Lens Corneal Refractive Therapy. Consider patient hygiene and mental and physical state. Collect and record baseline clinical information to which post-fitting examination results can be compared.

2. Initial Lens Power Selection

   Standard procedures for determining power of rigid gas permeable contact lenses may be used, including compensation for vertex distance.

3. Initial Lens Diameter Selection

   Usually, lens diameters between 9.0 mm to 11.0 mm are chosen to maximize centering to the cornea and to minimize lens movement. Lens diameters outside of this range are occasionally used for some eyes. This guide is only a general recommendation and the specification for an individual patient will depend on the eye care practitioner's professional judgment.

   Determining Starting Lens Diameter: The lens diameter is a function of the corneal diameter (horizontal visible iris diameter). The lens diameter should be between 1.0 to 2.0 mm less than the HVID. Lens centration is critical to the success of the treatment. Larger lens diameters may be needed to optimize centration.

4. Initial Lens Base Curve Selection

The base curve of the first lens fitted is generally fitted flatter than the flattest keratometric finding in an amount equal to the attempted reduction in myopia.

5. Initial Lens Evaluation

Movement: Blink induced lens movement should show minimal downward lens movement with the lid motion (average 1.0 mm.) and then upward with the lid motion (average 1.0 mm.) to a lesser degree than regular RGP contact lens. During the inter-blink period the lens should have little or no motion (average less than one millimeter).

Positioning: The lens should position centrally to minimize both lens movement and lid sensation. The lens should not ride more than 0.5 mm. below center nor 0.5mm. above center.

6. Characteristics of a Tight (too steep) Lens

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

7. Characteristics of a Loose (too flat) Lens

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

DIAGNOSTIC LENSES

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

Diagnostic Lens Set: A basic diagnostic lens set consists of approximately 20 base curves with one optic zone diameter and one total diameter. Each base curve should be available in three Reverse Curve selections to allow for Reverse Curve zone evaluation.

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

Eye care practitioners should educate contact lens technicians concerning proper care of diagnostic lenses. Each contact lens is shipped nonsterile in a case with no solution (dry). Therefore, in order to insure disinfection, clean and condition lenses prior to use. Hands should be thoroughly washed, rinsed and dried with a lint free towel prior to handling a lens.

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

Diagnostic Lens Procedure

Select a diagnostic lens and place the lens on the eye. Evaluate the lens using white light for the following:

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

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

3. Evaluate the Fluorescein Pattern: The fluorescein pattern should show a lens with definite central touch, approximately 3 to 5 mm diameter with a surrounding area of pooling. In the periphery there should be another area of lighter touch and near the edge a thin band of pooling.

The area of pooling near the transition between the base curve and secondary curve serves as a reservoir for tears and as a potential space for corneal shifting during the flattening process of Contact Lens Corneal Refractive Therapy. The cornea molds by flattening the central cornea, which reduces the space near the transition reservoir. Hence, the size of the transition reservoir, as observed from the fluorescein pattern, is a good indicator not only of the initial fit of the lens but also of the progress of corneal flattening over time as the lens is worn.

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

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

Limits of Flattening

In some cases the corneal flattening stops before a full reduction of the refractive error has been accomplished. Additional flattening may be possible by using a lens with a flatter secondary curve or a larger optic zone. If no further corneal flattening occurs, it is an indication that the cornea has reached a point of maximum change and the patient may require a design change for a retainer lens.

ORTHO-K PROBLEM SOLVING

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

1. CENTERING.
2. 1.0 mm MOVEMENT.
3. MODERATE APICAL TOUCH.
4. PATIENT COMFORT.

Problem	Possible Cause	Solution
Tight lens or no movement	Secondary Curve too steep Alignment Curve too steep Diameter too large	flatten Secondary Curve flatten Alignment Curve reduce Diameter
Loose lens	Secondary Curve too flat Alignment Curve too flat Diameter too small	steepen Secondary Curve steepen Alignment Curve increase Diameter
High-riding lens	Secondary Curve too flat Alignment Curve too flat Diameter too small	steepen Secondary Curve steepen Alignment Curve increase Diameter
Low-riding lens	Secondary Curve too flat or steep Diameter too small	steepen or flatten Secondary Curve increase Diameter
Flare, glare or ghosts	Optic Zone too small poor centration	increase Optic Zone increase Diameter
Fogging and scratchy lens	dirty lens improper care & handling of lenses improper blinking oily eye make-up removers	see "Lens Care"
Increase in corneal astigmatism	lens de-centered Diameter too small Secondary Curve or Alignment Curve too flat	improve centration increase Diameter steepen Secondary Curve or Alignment Curve
Poor VA with lenses	de-centered lens power error	improve centration check over-refraction
Poor VA w/out lenses	poor centration irregular corneal astigmatism lens overwear	steepen Secondary Curve or increase Diameter improve centration decrease wearing time and recheck

FOLLOW-UP CARE

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

2. Prior to a follow-up examination, the contact lenses should be worn overnight and the patient should be asked to identify any problems which occur that are related to contact lens wear.

3. With lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the cornea flattens rapidly there will be a larger area of central touch and the pooling at the lens transition will be reduced. The lens will usually show reduced movement. These are indications that the lens can be exchanged for another of flatter base curve. The additional degree of flattening is a function of the unaided acuity and residual refractive error measured upon lens removal. The base curve of the new lens can be flatter by the amount of residual myopic refraction. A corresponding steeper secondary curve may be required to avoid a loose lens-cornea relationship.

4. A lens with excessive movement should be replaced with another that is larger in diameter and approaches the corneal diameter less 1.0 to 1.5 mm OR with another that has a steeper or wider secondary (Reverse Zone) radius or width, OR with another that has a steeper Alignment Curve radius. If the cornea shows no flattening, this may be due to a base curve that is not flat enough or a secondary

curve that is too steep, resulting in "bridging". Bridging is caused by the outer junction of the secondary curve or the Alignment Curve having a heavy touch. The result of the touch is the lifting of the base curve off the cornea. When the base curve is lifted off the central cornea, it will not flatten the cornea, even if it is significantly flatter than the cornea it is covering. If the base curve has been selected to be flatter than the cornea equivalent to the attempted reduction in myopia, the failure to flatten most often resides in the secondary curve or Alignment Curve being too steep. In this case, the secondary curve and/or Alignment Curve should be made flatter by 0.2 to 0.4 mm until the fluorescein pattern demonstrates a proper central bearing of 3.0 to 5.0 mm.

5. After lens removal, conduct a thorough biomicroscopy examination to detect the following:

- The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
- The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of a reaction to solution preservatives, excessive lens wear, and/or a poorly fitted lens.

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 - Day 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

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 Quadra RG™ or Paragon Quadra RG™ 100 contact lenses for overnight 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.

HANDLING OF LENSES

Standard procedures for rigid gas permeable lenses may be used.

CAUTION: Paragon Quadra RG™ and Paragon Quadra RG™ 100 Contact Lenses for Corneal Refractive Therapy are shipped to the practitioner nonsterile. Clean and condition lenses prior to use.

PATIENT LENS CARE DIRECTIONS

Please see Package Insert of lens care product.

VERTEX DISTANCE AND KERATOMETRY CONVERSION CHARTS

Standard charts may be used.

HOW SUPPLIED

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

Each Paragon Quadra RG™ and Paragon Quadra RG™ 100 lens is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in Unique-pH™ Multi-Purpose Solution. This solution contains hydroxypropyl guar, a unique wetting and conditioning polymer system, polyethylene glycol, Tetronic*, boric acid, propylene glycol; and, is preserved with POLYQUAD® (polyquarternium-1) 0.0011% and edetate disodium 0.01%. The case, packing slip or invoice is marked with the central base curve radius, dioptric power, overall diameter, center thickness, lot number, fill date and the color of the lens.

* Registered Trademark of BASF corp.
Unique-pH™ is a Trademark of Alcon Laboratories, Inc.

Never reuse the solution. You may store the lenses in the unopened container until ready to dispense, up to a maximum of thirty (30) days from the Fill Date (see container). If the lenses are stored for longer periods of time, they should be cleaned and disinfected with an approved product (see product list in the Lens Care Directions section) 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
947 E. Impala Avenue
Mesa, Arizona 85204

1-800-528-8279
1-480-892-7602
1-480-926-7669 FAX

(Package Insert enclosed)
(Print date)

Attachment

PACKAGE INSERT

Paragon Quadra RG™

Manufactured in
Paragon HDS® (paflufocon B)

or

Paragon Quadra RG™ 100

Manufactured in
Paragon HDS® 100 (paflufocon D)

RIGID GAS PERMEABLE CONTACT LENSES FOR 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 law restricts this device to sale by, or on the order of a licensed practitioner.

Contact lenses for Corneal Refractive Therapy 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. 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 Quadra RG™ and Paragon Quadra RG™100
CONTACT LENSES FOR
CORNEAL REFRACTIVE THERAPY OVERNIGHT WEAR

DESCRIPTION

Paragon Quadra RG™ contact lenses are manufactured from Paragon HDS® and Paragon Quadra RG™ 100 contact lenses are manufactured from Paragon HDS® 100. The reverse geometry designs have posterior surfaces 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.

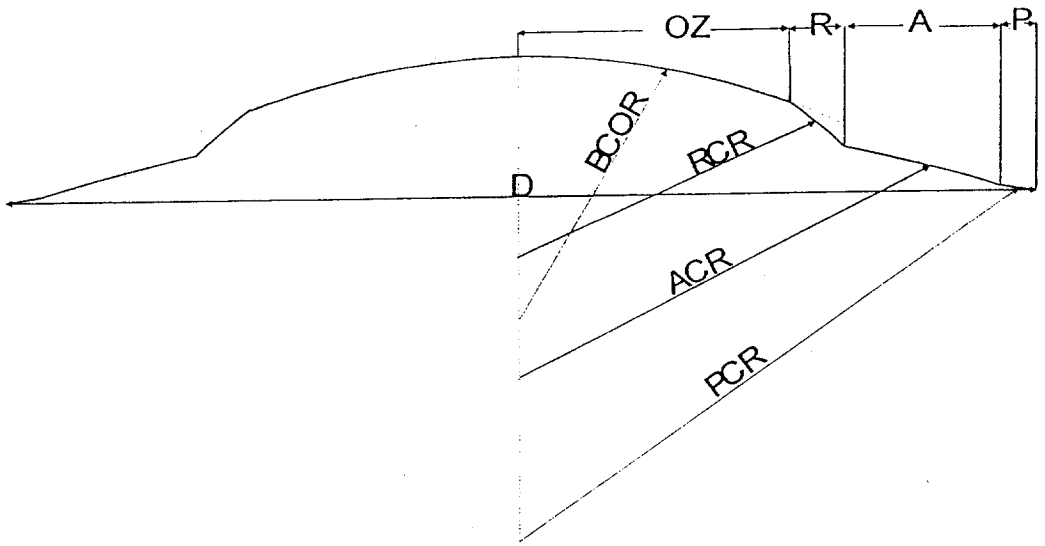
The lens design also includes a "rounded" edge terminus extending from the anterior to the posterior surfaces to promote comfort.

Paragon Quadra RG™ and Paragon Quadra RG™ 100 Contact Lenses for Corneal Refractive Therapy are to be worn overnight with removal during all or part of each following day. Both materials are 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 Refractive Therapy are available as lathe cut firm contact lenses with blue and green tints. The blue tinted lens contains D&C Green No. 6. The green lens contains D&C Green No. 6 and Perox Yellow No.9.

LENS PARAMETERS AVAILABLE (See drawing)

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)

149



ATTRIBUTES OF THE PARAGON Quadra RG™ LENS (paflufocon B)

Refractive Index	1.449 (Nd at 250 C)
Luminous Transmittance+ (Blue)	95%
Wetting Angle (Receding Angle)	14.7°
Specific Gravity	1.16
Hardness (Shore D)	84
Water Content	<1%

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

ATTRIBUTES OF THE PARAGON Quadra RG™ 100 LENS (paflufocon D)

Refractive Index	1.442 (Nd at 250 C)
Luminous Transmittance+ (Green)	95%
Wetting Angle (Receding Angle)	42°
Specific Gravity	1.10
Hardness (Shore D)	79
Water Content	<1%

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

OXYGEN PERMEABILITY - QUADRA RG™ LENS DESIGN****

Material	Power	Oxygen Permeability (Revised Fatt Method*) Dk x 10^{-11}	Oxygen Permeability (ISO Method**) Dk x 10^{-11}	Center Thickness (mm)	Harmonic Mean Thickness*** (mm)	Oxygen Transmissibility (Fatt) Dk/l x 10^{-9}	Oxygen Transmissibility (ISO) Dk/l x 10^{-9}
HDS 100	-2.00	145	100	0.180	0.194	75	52
HDS 100	Plano	145	100	0.200	0.190	76	53
HDS 100	+2.00	145	100	0.240	0.203	71	49
HDS	-2.00	58	40	0.180	0.194	30	21
HDS	Plano	58	40	0.200	0.190	31	21
HDS	+2.00	58	40	0.240	0.203	29	20

* (cm^2/sec) (mL O_2)/ (mL x mm Hg) Revised Method of I. Fatt
** (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.
**** The lens design is the generic 4 curve from Cho, et al. (Optom Vis Sci 2002;79:175-183)

ISO

ACTIONS

Paragon Quadra RG™ and Paragon Quadra RG™ 100 Contact Lenses for Contact Lens 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 Quadra RG™ and Paragon Quadra RG™ 100 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 Quadra RG™ and Paragon Quadra RG™ 100 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 Quadra RG™ (paflufocon B) and Paragon Quadra RG™ 100 (paflufocon D) 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 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 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 Quadra RG™ and Paragon Quadra RG™ 100 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 your contact lenses.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes become red or irritated.

WARNINGS

Paragon Quadra RG™ and Paragon Quadra RG™ 100 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,

151

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 Quadra RG™ and Paragon Quadra RG™ 100 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 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 Quadra RG™ and Paragon Quadra RG™ 100 contact lenses manufactured from Paragon HDS® and Paragon HDS® 100 respectively 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 Quadra RG™ and Quadra RG™ 100 design in the overnight wear modality was established partially on the basis of the experience with the Paragon CRT™ and Paragon CRT™ 100 design in the same lens materials. Therefore, some differences in efficacy may be observed.

Each Paragon Quadra™ and Paragon Quadra™ 100 lens is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in Unique-pH™ Multi-Purpose Solution. This solution contains hydroxypropyl guar, a unique wetting and conditioning polymer system, polyethylene glycol, Tetronic*, boric acid, propylene glycol; and, is preserved with POLYQUAD® (polyquarternium-1) 0.0011% and edetate disodium 0.01%. 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 unpreserved saline prior to cleaning, disinfecting and dispensing.

* Registered Trademark of BASF corp.
Unique-pH™ is a Trademark of Alcon Laboratories, Inc.

Never reuse the solution. You may store the lenses in the unopened container until ready to dispense, up to a maximum of thirty (30) days from the Fill Date (see container). If the lenses are stored for longer periods of time, they should be cleaned and disinfected with a recommended product (see product list in the Lens Care Directions section), 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 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.

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, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.

- 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 the Quadra RG™ 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 Refractive Therapy performed with those lens designs in accordance with their approved indications and labeling.

I. Paflufocon B in Quadra RG™ (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 orthokeratology 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.

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

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.

Paragon Quadra RG™ contact lenses for orthokeratology 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.

155

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 VA 20/20 or better	FINAL VA 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 orthokeratology. 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 orthokeratology 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 2 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.

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.

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.

Summary of Key Safety Variables (N=184)		
Criteria	3 Months	
	n	%
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

CLINICAL STUDY DATA

INTRODUCTION

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.

DEMOGRAPHIC INFORMATION

A total of 205 subjects (408 eyes) were enrolled and treated comprising of 188 Caucasians, 1 African American, 13 Asian/Pacific Islanders, and 3 Hispanics. Data on 121 subjects (240 eyes) were analyzed following 9 months of treatment. There were 73 female and 48 male patients. The mean age of these subjects was 35 years (ranging from 12 to 56 years).

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

158

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 VA 20/20 or better**	FINAL VA 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)

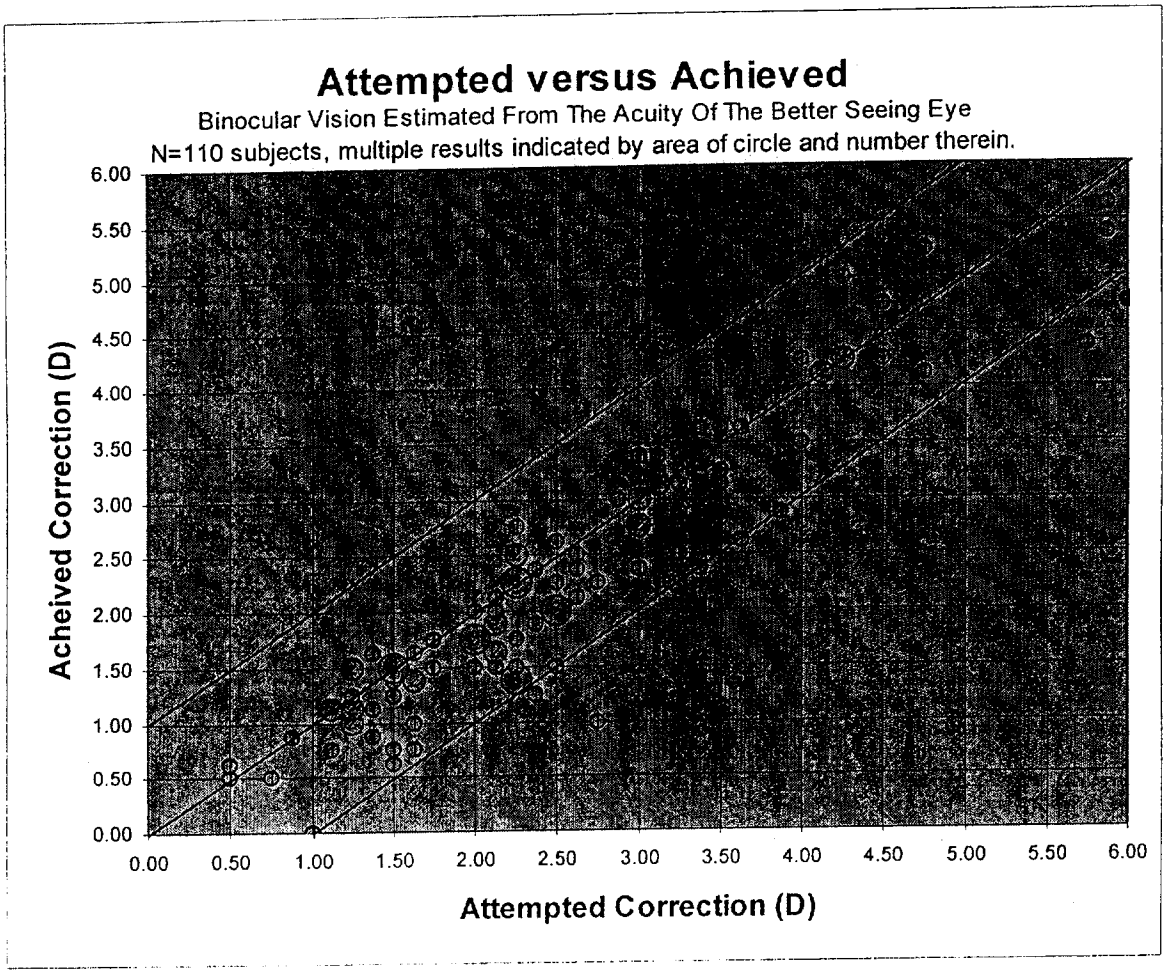
Accuracy

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 below graphically depicts the accuracy of the treatment.

[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

159



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 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 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 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.

16C

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.

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

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, 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.

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

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 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).

FITTING, (Quadra RG™ and Quadra RG™ 100)

Note: Contact lenses for Corneal Refractive Therapy should be fitted only by a trained and certified contact lens fitter.

Conventional methods of fitting rigid contact lenses DO NOT APPLY to the Quadra RG™ and Paragon Quadra RG™ 100 Contact Lenses for Corneal Refractive Therapy. For a description of fitting techniques, refer to the Professional Fitting And Information Guide - Paragon Quadra RG™ and Paragon Quadra RG™ 100. Copies are available from:

Paragon Vision Sciences
947 E. Impala Avenue
Mesa, Arizona 85204-6619

RECOMMENDED INITIAL WEARING SCHEDULE, (Quadra RG™ and Quadra RG™ 100)

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 - Day 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

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 Quadra RG™ or Paragon Quadra RG™ 100 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.

160

LENS CARE DIRECTIONS

The following is a list of products available for use with Paragon Quadra RG™ and Paragon Quadra RG™ 100 rigid gas permeable contact lenses. This is not an exclusive list. You may use other lens care solutions as recommended by your eye care practitioner.

SYSTEM PROCESS	CHEMICAL (not heat) DISINFECTION SYSTEM
Cleaning	Unique-pH™ Multi-Purpose Solution, SupraClens®, Opti-Clean® II, Opti-Zyme®, Barnes-Hind® GP Daily Cleaner, LC-65®, Pro-Free/GP®
Disinfection	Unique-pH™ Multi-Purpose Solution, Barnes-Hind® GP Wetting and Soaking Solution, Wet-N-Soak® Plus
Lubrication	Clerz® Plus, Opti-Tears®, Refresh Contacts™, Wet-N-Soak® Rewetting Drops

PRODUCT LIST

Unique-pH™ Multi-Purpose Solution, SupraClens®, Clerz® Plus, Opti-Clean® II, Opti-Zyme®, Opti-Tears® by Alcon Laboratories, Inc.

Barnes-Hind® GP Daily Cleaner, LC-65®, ProFree/GP®, Barnes-Hind® GP Wetting and Soaking Solution, Wet-N-Soak® Plus, Wet-N-Soak® Rewetting Drops by Allergan Pharmaceuticals

The directions found in the package inserts from these products should be followed. 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.
- Quadra RG™ and Paragon Quadra RG™ 100 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.
- Clean one lens first. The recommended procedure is to always clean the same lens first to avoid mix-ups. Rinse the lens thoroughly 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 Quadra RG™ and Paragon Quadra RG™ 100 lens is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in Unique-pH™ Multi-Purpose Solution. This solution contains hydroxypropyl guar, a unique wetting and conditioning polymer system, polyethylene glycol, Tetronic*, boric acid, propylene glycol; and, is preserved with POLYQUAD® (polyquarternium-1) 0.0011% and edetate disodium 0.01%. The case, packing slip or invoice is marked with the central base curve radius, dioptric power, overall diameter, center thickness, lot number, fill date and the color of the lens.

*Registered Trademark of BASF corp.
Unique-pH™ is a Trademark of Alcon Laboratories, Inc.

Never reuse the solution. You may store the lenses in the unopened container until ready to dispense, up to a maximum of thirty (30) days from the Fill Date (see container). If the lenses are stored for longer periods of time, they should be cleaned and disinfected with a recommended product (see product list in the Lens Care Directions section), 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
947 E. Impala Avenue
Mesa, Arizona 85204-6619

1-800-528-8279
1-480-892-7602
1-480-926-7369 FAX

(Print date)

Considering Contact Lens Corneal Refractive Therapy™?

Patient Information Booklet for Potential Users of
Paragon Quadra RG™ and Paragon Quadra RG™ 100
Contact Lens Corneal Refractive Therapy

PATIENT INFORMATION BOOKLET
FOR POTENTIAL USERS OF

Paragon Quadra RG™

Manufactured in Paragon HDS® (paflufocon B)

Or

Paragon Quadra RG™ 100

Manufactured in Paragon HDS® 100 (paflufocon D)

Contact Lenses For
Contact Lens Corneal Refractive Therapy

Overnight Wear

CAUTION: Federal law restricts this device to sale by, or on the order of a licensed practitioner.

Contact lenses for Corneal Refractive Therapy should be fitted only by a trained and certified contact lens fitter. Nonsterile. Clean and condition lenses prior to use.

168

TABLE OF CONTENTS

INTRODUCTION

The information in this booklet is to help you decide whether or not to be fitted with Paragon Quadra RG™ and Paragon Quadra RG™ 100 lens designs for Contact Lens Corneal Refractive Therapy. Contact Lens Corneal Refractive Therapy is a fitting procedure that temporarily corrects or greatly reduces nearsightedness (known by the medical name, myopia) with or without astigmatism after contact lenses have been removed. By temporary, it is meant that the contact lenses are worn while sleeping (overnight) and then removed upon awaking; whereupon the nearsightedness remains corrected or greatly reduced for all or most of your waking hours. The exact time period over which the myopia remains corrected varies with each patient. Generally, Paragon Quadra RG™ and Paragon Quadra RG™ 100 lens designs for Contact Lens Corneal Refractive Therapy must be worn each night to maintain the effect.

Note: Contact lenses for Corneal Refractive Therapy should be fitted only by a trained and certified contact lens fitter.

HOW THE EYE FUNCTIONS

The eye is very much like a camera and must be in good focus to see objects clearly. The focusing power of the eye comes from two eye structures, the cornea and the lens (Figure 1).

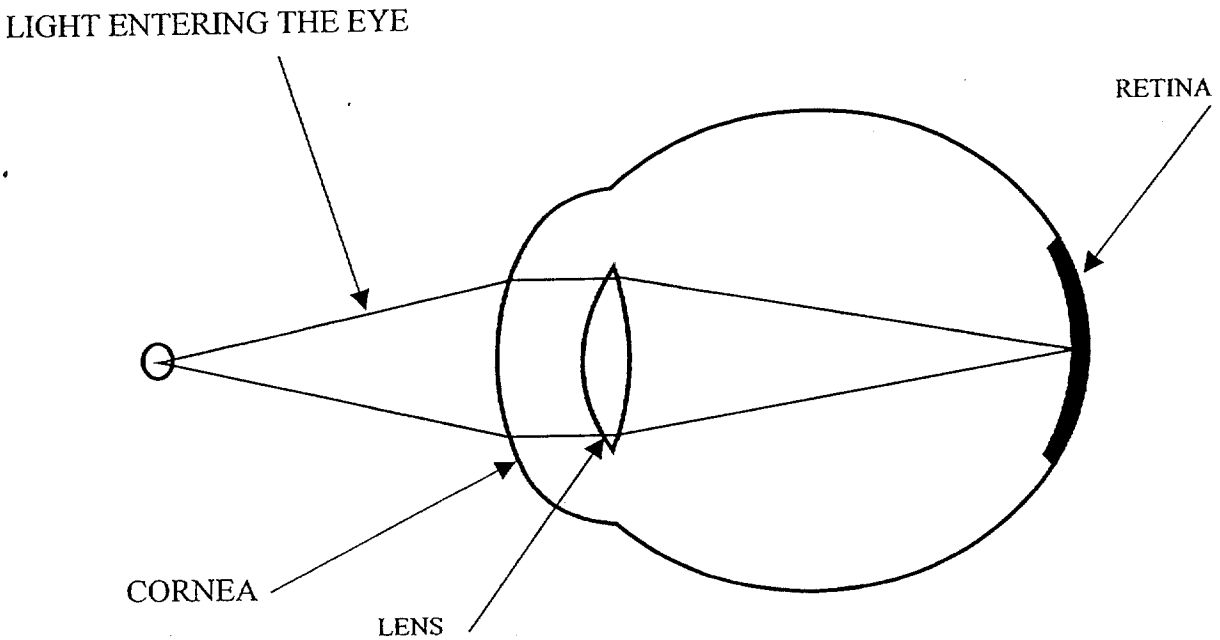


Figure 1: Normal Eye

The cornea is the clear, bubble-like structure on the front of the eye, where light first enters the eye. It provides about two thirds of the eye's focusing power, and the lens inside the eye provides the other third. In a normal eye light focuses at the retina, at the back of the eye, which acts like the film in a camera.

Some eyes focus, or refract, the light too much, so that the images of distant objects are formed in front of the retina, and the image on the retina is blurred, producing myopia (Figure 2).

170

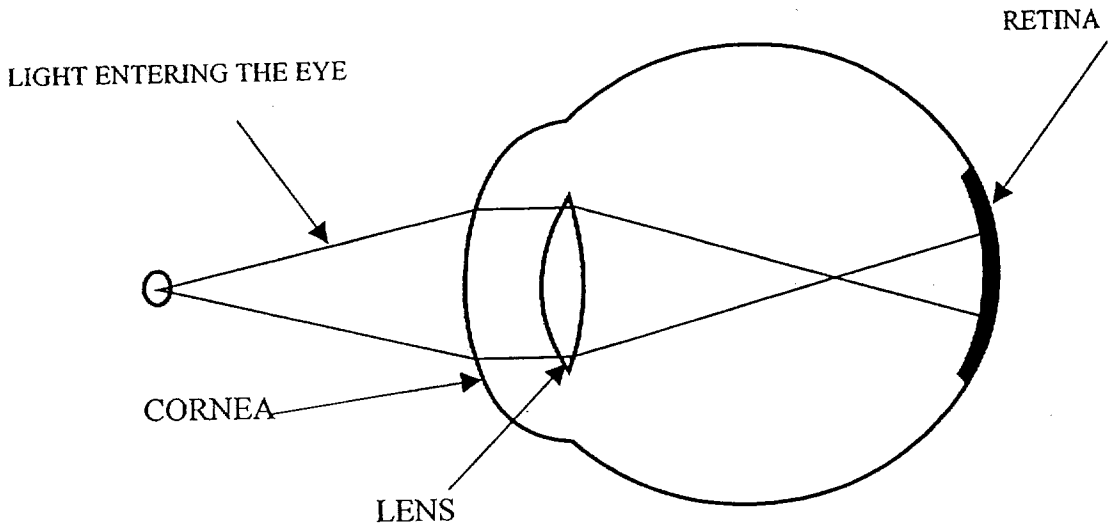


Figure 2: Nearsighted Eye

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

HOW PARAGON QUADRA RG™ AND PARAGON QUADRA RG™ 100 CONTACT LENSES FOR CONTACT LENS CORNEAL REFRACTIVE THERAPY FUNCTION

These contact lens designs for Corneal Refractive Therapy produce a temporary reduction of nearsightedness by changing the shape (by flattening) of the cornea, which is elastic in nature. Contact lenses rest gently on the cornea, separated only by a layer of tears, and can influence the corneal shape. Regular contact lenses are designed to nearly match the shape of the cornea and thereby cause little or no flattening effect. Paragon Quadra RG™ and Paragon Quadra RG™ 100 Contact Lenses for Contact Lens Corneal Refractive Therapy are designed purposely not to match the shape of the cornea, but instead to apply slight pressure to the center of the cornea (Figure 3).

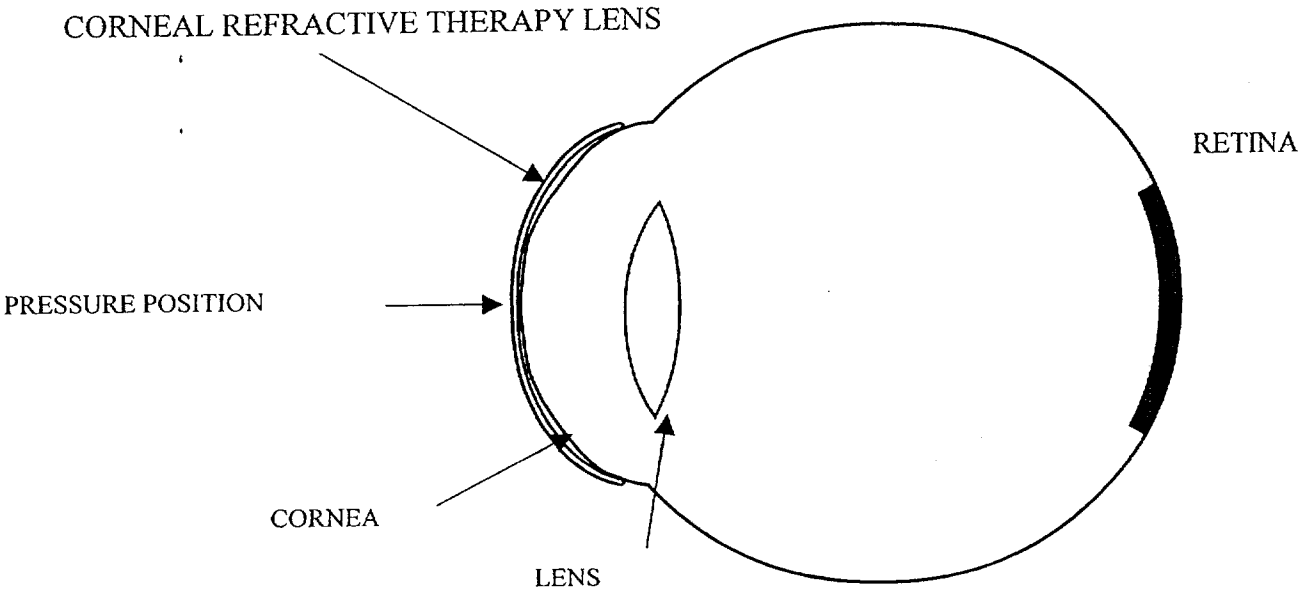


Figure 3: Eye Fitted With A Paragon Quadra RG™ or Paragon Quadra RG™ 100 Contact Lens For Contact Lens Corneal Refractive Therapy

171

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

If the cornea is flattened this reduces the focusing power of the eye, and if the amount of corneal flattening is sufficient, it is possible to bring the eye into correct focus and compensate for myopia (Figure 4).

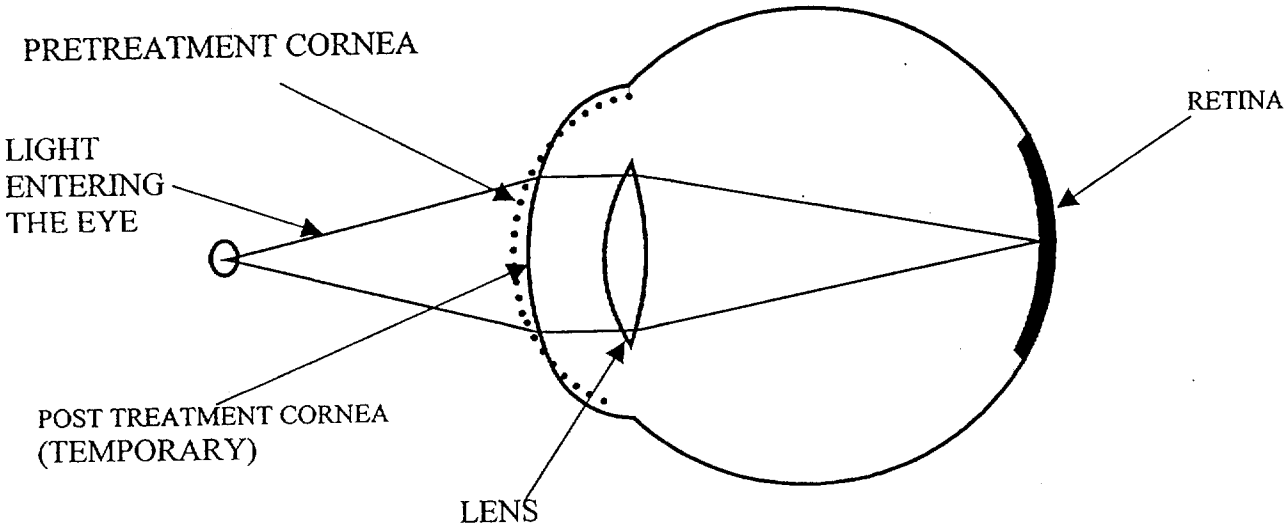


Figure 4: Nearsighted Eye After Contact Lens Corneal Refractive Therapy

Paragon Quadra RG™ and Paragon Quadra RG™ 100 Contact Lenses for Contact Lens Corneal Refractive Therapy are generally worn overnight. After the lens is removed, the cornea retains its altered shape and corrected focus for all or most of your waking hours.

These contact lenses for Corneal Refractive Therapy are indicated for patients who want to see clearly during their daily activities, free from the inconvenience of traditional contact lenses or spectacles. Paragon Quadra RG™ and Paragon Quadra RG™ 100 Contact Lenses for Corneal Refractive Therapy may also be indicated for occupations that require exposure to smoke, noxious gases or conditions of low humidity.

These contact lenses for Corneal Refractive Therapy 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 on your eye.

ALTERNATIVE WAYS TO CORRECT NEARSIGHTEDNESS

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

RISK ANALYSIS

There is a small risk involved when any contact lens is worn. It is not expected that Paragon Quadra™ or Paragon Quadra™ 100 contact lenses for orthokeratology will provide a risk that is greater than other rigid gas permeable contact lenses.

The two most common side effects, which occur in rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that these two side effects will also occur in some wearers of Paragon Quadra™ or Paragon Quadra™ 100 contact lenses for orthokeratology. Other side effects, which sometimes occur in all

177

hard contact lens wearers are pain, redness, tearing, irritation, discharge, abrasion of the eye or distortion of vision. These are usually temporary conditions if the contact lenses are removed promptly and professional care is obtained. When overnight orthokeratology lenses dislocate during sleep, transient distorted vision may occur the following morning after removal of the lenses. This distortion may not be immediately corrected with spectacle lenses. The duration of distorted vision would rarely be greater than the duration of the daily visual improvement normally achieved with the lenses.

In rare instances, there may occur permanent corneal scarring, decreased vision, infections of the eye, corneal ulcer, iritis, or neovascularization. The occurrence of these side effects should be minimized or completely eliminated if proper schedule of care is followed. You should remove your contact lenses if any abnormal signs are present.

INDICATIONS

Paragon Quadra RG™ (paflufocon B) and Paragon Quadra RG™ 100 (paflufocon D) 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 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 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.

PRECAUTIONS

General

Clinical studies have demonstrated that Paragon Quadra RG™ and Paragon Quadra RG™ 100 contact lenses manufactured from Paragon HDS® and Paragon HDS® 100 respectively 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 your ocular health; including, oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The potential impact of these factors on your ocular health should be carefully weighed against your need for refractive reduction; therefore, your continuing ocular health and lens performance on the eye should be carefully monitored by your prescribing eye care practitioner. Corneal edema is more prevalent when the lens is used in high altitudes.

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

Each Paragon Quadra™ and Paragon Quadra™ 100 lens is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in Unique-pH™ Multi-Purpose Solution. This solution contains hydroxypropyl guar, a unique wetting and conditioning polymer system, polyethylene glycol, Tetronic*, boric acid, propylene glycol; and, is preserved with POLYQUAD® (polyquarternium-1) 0.0011% and edetate disodium 0.01%. 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 unpreserved saline prior to cleaning, disinfecting and dispensing.

* Registered Trademark of BASF corp.
Unique-pH™ is a Trademark of Alcon Laboratories, Inc.

173

Never reuse the solution. You may store the lenses in the unopened container until ready to dispense, up to a maximum of thirty (30) days from the Fill Date (see container). If the lenses are stored for longer periods of time, they should be cleaned and disinfected with a recommended product (see product list in the Lens Care Directions section). Follow the directions on the selected disinfecting solution regarding prolonged storage.

Patient

You should be aware of the following precautions.

Solution Precautions

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions with the contact lenses.
- Do not heat the wetting/soaking solution and lenses.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts of the 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 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 your hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in your eyes and/or on your 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 your hand rather than between the thumb and fingers.

Lens Wearing Precautions

- CAUTION: Nonsterile. Clean and condition lenses prior to use.
- If the lens sticks (stops moving) on your 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 your eyes closed until the spray has settled.

Lens Case Precautions

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eye care practitioner.

Discuss these topics with your eye care practitioner:

- Wear of contact lenses during sporting activities.
- Use of any medication in your eyes.
- Importance of adhering to the recommended follow-up schedule to assure the continuing health of your eyes.
- Informing your doctor (health care practitioner) about being a contact lens wearer.
- Informing your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses during work hours.

CONTRAINDICATIONS (REASONS NOT TO USE)

DO NOT USE Paragon Quadra RG™ and Paragon Quadra RG™ 100 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 your contact lenses.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes become red or irritated.

17

WARNINGS

Paragon Quadra RG™ and Paragon Quadra RG™ 100 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 Quadra RG™ and Paragon Quadra RG™ 100 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 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.

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 the Quadra RG™ 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 Refractive Therapy performed with those lens designs in accordance with their approved indications and labeling.

I. Paflufocon B in Quadra RG™ (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 orthokeratology 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.

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

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.

Paragon Quadra RG™ contact lenses for orthokeratology 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 orthokeratology. 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 orthokeratology 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 best spectacle-corrected visual acuity losses, biomicroscope exam, 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.

Biomicroscope Exam (Quadra RG™)

Investigator examinations with the biomicroscope reported 2% mild observations (20 reports) and a single moderate report related to the lens care solution. There was a pattern of increased trace corneal staining through the course of the study.

Symptoms, Complaints and Discontinuations (Quadra RG™)

Subjects were asked to report symptoms and complaints during the study. The symptoms of discomfort, itching and dryness are persistent throughout the clinical study. The reverse geometry lenses may demonstrate less comfort than conventional designs manufactured in the same material.

Of the 92 subjects who were dispensed lenses, 35 were discontinued. 17 were voluntarily withdrawn since they were not able to continue their follow-up visits, 12 had clinical reasons such as unacceptable fit or vision or lack of comfort and 6 lost interest or moved.

Adverse Events and Complications, (Quadra RG™)

There were no severe adverse events reported in this study. 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.

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

INTRODUCTION

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.

DEMOGRAPHIC INFORMATION

A total of 205 subjects (408 eyes) were enrolled and treated comprising of 188 Caucasians, 1 African American, 13 Asian/Pacific Islanders, and 3 Hispanics. Data on 121 subjects (240 eyes) were analyzed following 9 months of treatment. There were 73 female and 48 male patients. The mean age of these subjects was 35 years (ranging from 12 to 56 years).

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

EFFECTIVENESS OUTCOMES, (OVERNIGHT CRT™ DESIGN)

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

*All Efficacy Qualified Patients

170

Uncorrected Visual Acuity (UCVA), (CRT™)

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, (CRT™)

Accuracy of outcome was evaluated by analysis of attempted versus achieved manifest refraction spherical equivalent. At the 9-month visit, 70% (153/220) of 9-month efficacy qualified eyes were within 0.50 D attempted 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.

Wearing Time, (CRT™)

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.

[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

182

Regression Of Visual Acuity, (CRT™)

The effects of wearing your lenses at night are not permanent and begin to diminish slowly as soon after you remove your lenses. For most wearers this does not present a problem but it is important to realize for some patients their vision at the end of the day may not be fully satisfactory for tasks with high visual demand. For most wearers this will not be an issue. You must consider your own late-in-the-day circumstances to decide if it is a concern. As you will see the higher your original correction needs, the better your treatment must be to assure a full day of uncompromising vision

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. The following table estimates how long after lens removal before your vision regresses to 20/40, which is the lower limit for visual acuity at which you are still allowed to drive without glasses in most states.

To use the table you need to know your original spectacle correction (power of your glasses or contacts). By finding your correction in the third row of the table and looking at the time ranges in the column below it, you will see typical times that persons like yourself might experience.

The top range in your column is for persons whose treatment has been fully successful. As you go down the column you see values for less successful treatments. If you have high corrective needs, discuss this with your eye care practitioner before deciding if CRT is right for you.

		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

There are remedies for special circumstances when you find yourself in need of excellent vision at longer times than the success of your treatment offers. One of these is to reinsert your Paragon CRT lenses. You may do this at anytime, for any reason and you will always immediately have optimum vision with the lenses in you eyes. Ask your eye care practitioner about other options available to you in such circumstances.

Effects On Astigmatism, (CRT™)

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, (CRT™)

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, biomicroscope exam and symptoms and complaints. The analysis was completed for all eyes that reported at all visits.

Best Spectacle-Corrected Visual Acuity (BSCVA), (CRT™)

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 acuity loss was due to optical distortion of the corneal.

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, (CRT™)

This analysis was based on discontinued eyes. Only eyes with 3 or more weeks of treatment were included in this analysis in order to gain a more accurate mesure of recovery time. Those eyes with an average treatment of 3 months and scheduled post discontinuation follow-up, had a mean recovery of less than 2 weeks. Of the eyes meeting the discontinuation follow up criteria, 67% (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.

Biomicroscope exam, (CRT™)

Biomicroscope examination of the eye documented 4% mild and less than 1% moderate reports during the study. There were no severe observations reported.

The 28 moderate reports cited included edema (18), staining (9) and injection (1). Seventeen of the 18 reports of edema were at one site located at more than 7000 feet above sea level. All 28 cases resolved without further complication.

Symptoms, Complaints and Discontinuations (CRT™)

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 who were dispensed lenses, 83 were discontinued. 52 had clinical reasons such as unacceptable vision (44) or lack of comfort (8). 12 Subjects lost interest, 18 were lost to follow-up or missed visits and one subject became pregnant and discontinued at the 6-month follow-up visit.

Adverse Events and Complications, (CRT™)

There were no severe adverse events reported in this study. There were no persistent losses or reductions of sight attributable to treatment during the course of this trial. Four study related complications were reported, two rated as mild and two rated as moderate severity. All reported complications resolved with no sequelae.

Summary of Key Safety Variables, (CRT™)

Many of the key safety issues evaluated in the study were related to assuring that no long-term detrimental changes to subjects eyes were taking place In fact no evidence of any permanent changes of any kind were observed. During treatment however, for a small number of patients, there were some small transient changes in astigmatism. About 1 % of patients had increases in refractive (visual) astigmatism more than one diopter. About 4 % of patients had increases in corneal cylinder (uneven corneal curvature) greater than one diopter but it did not result in more than one diopter of refractive (visual) astigmatism.

In the cases where patients had an increase in astigmatism and opted to leave the study (usually for other reasons) their eyes subsequently returned to their original pretreatment condition with no residual refractive or corneal astigmatism.

Patient Satisfaction, (CRT™)

Based on their experience with their habitual correction (spectacles or contact lenses) pretreatment, 81% of subjects rated their overall satisfaction of their vision very good or excellent. 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.

MAINTAINING EFFECTS OF PARAGON QUADRA RG™ AND PARAAGON QUADRA RG™ 100 LENSES FOR CORNEAL REFRACTIVE THERAPY

The long-term wear of Paragon Quadra RG™ and Paragon Quadra RG™ 100 Contact Lenses for Corneal Refractive Therapy does not eliminate the need to continue wearing contact lenses to produce the reduction in myopia. After the cornea has been changed by wearing these contact lenses, you must continue overnight wear of lenses to maintain the results. Usually the treatment lenses will continue to be the lenses worn after successful treatment. In unusual circumstances, new lenses may be prescribed that are Myopic Reduction Maintenance Lenses or Retainer Lenses. Such Retainer Lenses would be only a slight modification of your Paragon Quadra RG™ or Paragon Quadra RG™ 100 prescription.

The wearing schedule for Paragon Quadra RG™ and Paragon Quadra RG™ 100 contact lenses or Retainer Lenses may vary from the schedule prescribed during treatment. In cases of low pretreatment myopia, the effect may last for more than one day.

Note: To maintain the 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.

GLOSSARY

Adnexa	Tissues near to the eye
Adverse Effects	Undesirable effects
Aphakia	Eye that does not have a lens structure
Astigmatism	Eye condition in which one or more surfaces of the cornea or lens has a shape that is not round but more like that of a spoon
Biomicroscope	An instrument that uses magnification to examine the eye
Best Spectacle Corrected Visual Acuity	Best vision you can achieve wearing glasses in your exact prescription under optimum viewing conditions
Contact Lens Corneal Refractive Therapy	Contact lens fitting procedure that results in a reduction of nearsightedness while lenses are worn and for a temporary period after the contact lenses have been removed (typically 1 day if worn overnight)
Contact Lens Sticking	Lack of movement of a contact lens on the cornea
Cornea	The clear, bubble-like structure on the front of the eye, where light first enters the eye
Corneal Abrasion	Loss of cells on the corneal surface due to mechanical trauma
Corneal Edema	Accumulation of fluid in the cornea resulting in swelling
Corneal Hypoesthesia	Partial loss of sensitivity to touch in the cornea
Corneal Staining	Bright areas on the cornea where dye collects and which indicates an abrasion or other disturbance of the cornea
Corneal Ulcer	Small area of tissue loss in the cornea
CRT	Corneal Refractive Therapy
Disinfection	Destruction of bacteria and viruses but not some spores
Diopter	Unit of power for glasses or contact lenses
Enzyming Contact Lenses	Placing contact lenses in a solution that contains an enzyme that dissolves proteins on the surface of the lens
Iritis	Infection of the iris or colored portion of the eye
Lacrimal Secretion	Tearing
Manifest Refraction Spherical Equivalent	A measure of vision correction requirements (in diopters), which combines your myopia and your astigmatism

Myopia	Medical term for nearsightedness
Myopic Reduction Maintenance Lens	A modification of the Corneal Refractive Therapy contact lens design in which the central portion of the lens applies just enough pressure to the cornea to maintain the corneal flattening achieved but with no additional corneal flattening. Such a lens is usually not needed with Paragon Quadra RG since the treatment lens performs this function.
Neovascularization	New blood vessel growth in the cornea
Orthokeratology	Predecessor to Contact Lens Corneal Refractive Therapy using a series of lenses to achieve a temporary reduction in myopia
Refract	Bending of light in order to make it focus
Refractive Anomalies	Eye conditions leading to blurred vision including nearsightedness, farsightedness and astigmatism
Retainer Lens	Another name for the Myopic Reduction Maintenance Lens
Retina	Structure at the back of the eye that receives the light image
Rewetting Contact Lenses	Placing a solution in the eye while contact lenses are worn that acts as an artificial tear to wet the lens
Sticking Lens	Lens on the cornea that does not move

Manufacturer:

Paragon Vision Sciences
947 E. Impala Avenue
Mesa, Arizona 85204-6619

1-800-528-8279
1-480-892-7602
1-480-926-7369 FAX

(Package Insert enclosed)
(Print date)

18C