

Considering Contact Lens CORNEAL RESHAPING

PATIENT INFORMATION BOOKLET
FOR POTENTIAL USERS OF

OrthoTool™ Software Design

Manufactured in Paragon HDS® 100 (paflucocon D)

**Contact Lenses For
Contact Lens Corneal Reshaping**

Overnight Wear

CAUTION: Federal (US) law restricts this device to sale by, or on the order of a licensed practitioner.
Contact lenses for corneal reshaping should be fitted only by a trained and certified contact lens fitter.
Nonsterile. Clean and condition lenses prior to use.

TABLE OF CONTENTS

	<u>Page</u>
Introduction	1
How The Eye Functions	1
How Ortho Tool Software Design Contact Lenses For Corneal Reshaping Function	2
Alternative Ways To Correct Nearsightedness	3
Risk Analysis	3
Indications	3
Precautions	3
Contraindications (Reasons Not To Use)	4
Warnings	4
Adverse Effects (Problems And What To Do)	4
Clinical Study Data	4
Overnight Wear Safety Summary	7
Maintaining Effects Of Ortho Tool Software Design Lenses For Corneal Reshaping	8
Glossary	8

INTRODUCTION

The information in this booklet is to help you decide whether or not to be fitted with Ortho Tool Software Design for Contact Lens Corneal Reshaping. Corneal reshaping 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, Ortho Tool Software Design lens designs for Contact Lens Corneal Reshaping must be worn each night to maintain the effect.

Note: Contact lenses for corneal reshaping 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).

LIGHT ENTERING THE

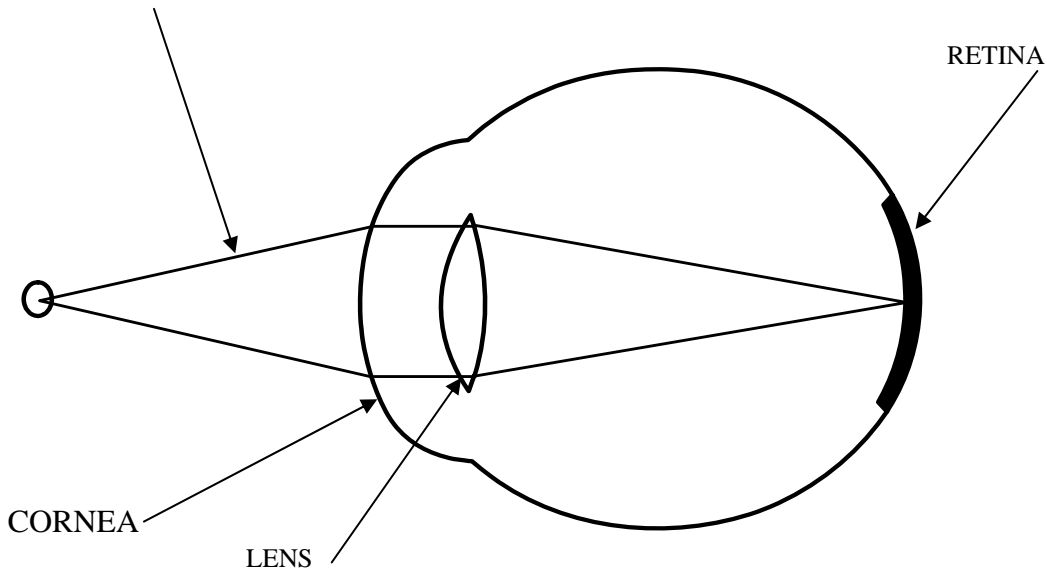


Figure 1: Normal Eye

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).

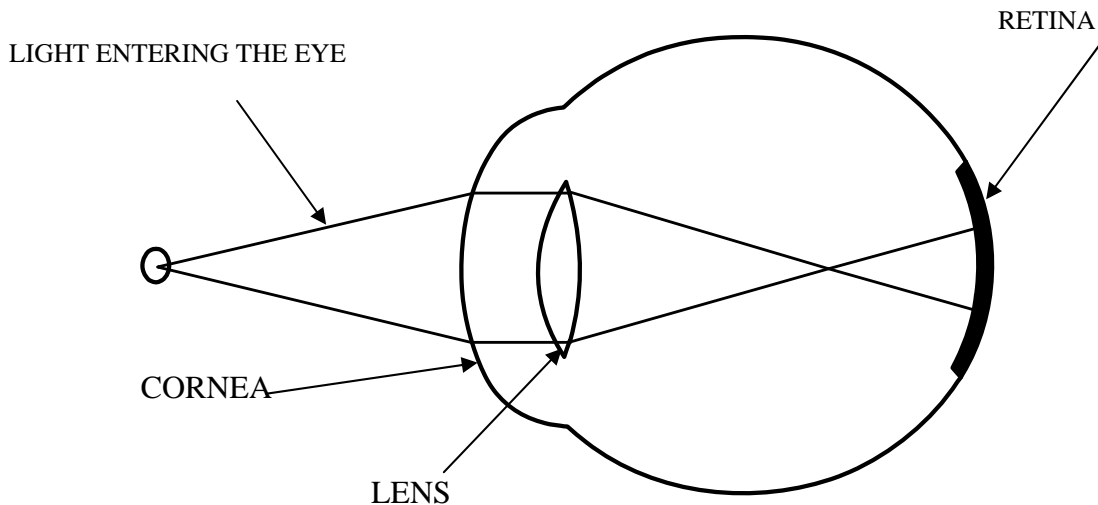


Figure 2: Nearsighted Eye

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 ORTHO TOOL SOFTWARE DESIGN CONTACT LENSES FOR CORNEAL RESHAPING FUNCTION

This contact lens designs for corneal reshaping 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. Ortho Tool Software Design Contact Lenses for Contact Lens Corneal Reshaping 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).

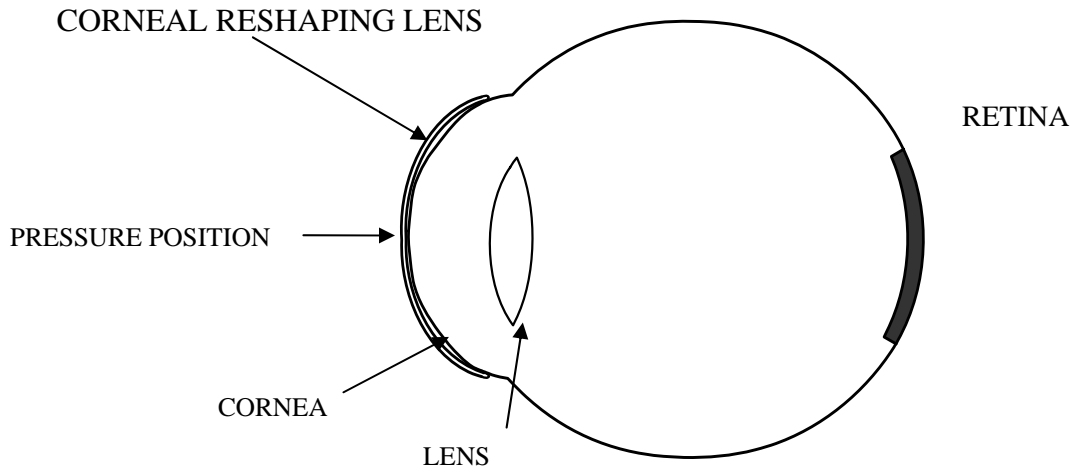


Figure 3: Eye Fitted With A Ortho Tool Software Design Contact Lens For Contact Lens Corneal Reshaping

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).

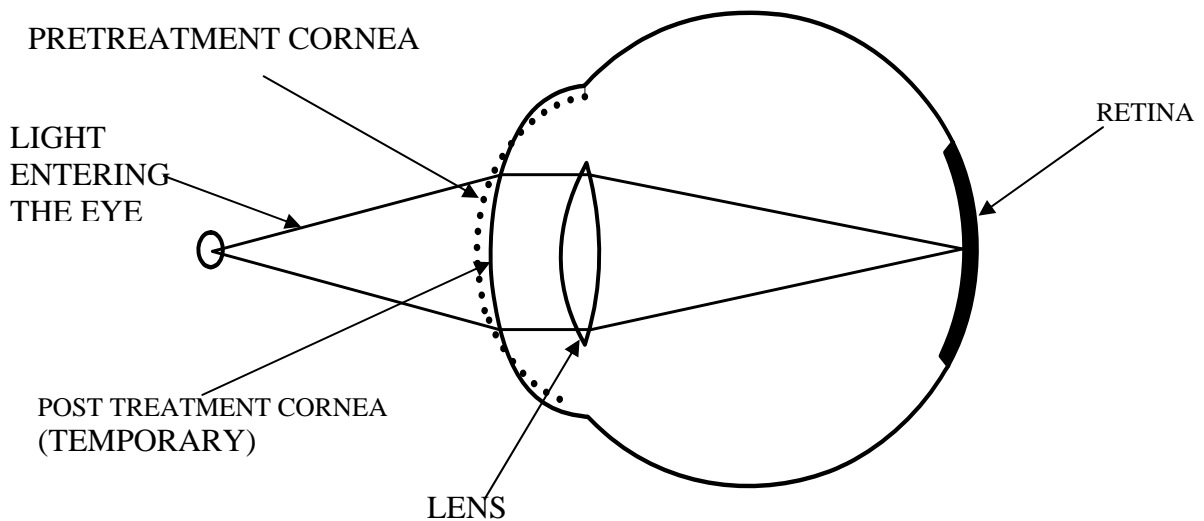


Figure 4: Nearsighted Eye After Contact Lens Corneal reshaping

Ortho Tool Software Design Contact Lenses for Contact Lens Corneal Reshaping 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 reshaping are indicated for patients who want to see clearly during their daily activities, free from the inconvenience of traditional contact lenses or spectacles. Ortho Tool Software Design Contact Lenses for Corneal Reshaping may also be indicated for occupations that require exposure to smoke, noxious gases or conditions of low humidity.

These contact lenses for corneal reshaping 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 Ortho Tool Software Design Contact Lenses for Corneal Reshaping 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 Ortho Tool Software Design Contact Lenses for Corneal Reshaping. 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 corneal reshaping lenses dislodge 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

Ortho Tool Software Design (paflucon D) rigid gas permeable contact lenses for corneal reshaping are indicated for use in the reduction of myopic refractive error in nondiseased eyes. The lenses are indicated for overnight wear in a corneal reshaping fitting program for the temporary reduction of up to 3.00 diopters of myopia in eyes with astigmatism up to 1.50 diopters. The lenses may be disinfected using only a chemical disinfection system.

Note: To maintain the corneal reshaping effect of myopia reduction overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving), visual fluctuations and changes in intended correction.

PRECAUTIONS

General

Clinical studies have demonstrated that Ortho Tool Software Design contact lenses manufactured from 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 Ortho Tool Software Design in the overnight wear modality was established partially on the basis of the experience with the Paragon CRT™ 100 design in the same lens materials. Therefore, some differences in efficacy may be observed.

Ortho Tool Software Design is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in solution. This solution contains poloxamine, hydroxyalkylphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%). The case, packing slip or invoice is marked with the base curve radius, dioptric power, diameter, center thickness, inclusion of UV absorber, serial number, fill date and the color of the lens.

Never reuse the solution. You may store the lens in the unopened container until ready to dispense, up to a maximum of thirty (30) days from the Fill Date. When a lens has been stored for 30 days in its original packaging solution, it should be cleaned and disinfected with an FDA approved product, and placed into inventory as you presently do with any other RGP lens held in your office. Follow the directions on the selected disinfecting solution regarding prolonged storage.

Patient

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, tap water or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored).

Handling Precautions

- Always wash and rinse 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 Ortho Tool Software Design Contact Lenses for Corneal Reshaping when any of the following conditions exist:

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

WARNINGS

Ortho Tool Software Design Contact Lenses for Corneal Reshaping are shipped to the practitioner nonsterile. Clean and condition lenses prior to use.

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

Ortho Tool Software Design Contact Lenses for Contact Lens Corneal Reshaping are to be worn overnight with removal during all or part of each following day. Wearing the lenses continuously (extended wear) presents increased risk, which increases with the number of consecutive days that the lenses are worn between removals. Although overnight Contact Lens Corneal Reshaping prescribes only overnight wear with removal during the waking hours, and although the safety risks of intermittent overnight wear may not be as great as with sustained overnight wear; there is still increased risk beginning with the first overnight period.

WARNING

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

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

ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

Patients should be informed that the following problems may occur.

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

If the patient notices any of these conditions, the patient should IMMEDIATELY REMOVE YOUR LENSES. The patient should follow these instructions.

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

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

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 reshaping performed with those lens designs, and the Ortho Tool Software Design in accordance with their approved indications and labeling.

I. Pafufocon 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 Corneal Reshaping 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 Corneal Reshaping 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.

* Although the trade name Quadra RG™ 100 was used to designate the reverse geometry design used in the daily wear study, the Ortho Tool Software Design is a lens of that design and the references to Quadra RG™ in this clinical data should be considered applicable to the Ortho Tool Software Design.

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

For the patients (114 eyes) that completed this study, the initial visual acuity by best refraction was 20/20 or better for 84 (74%) eyes and 20/40 or better for all eyes. At the final visit, visual acuity with contact lenses was equal to or better than 20/20 for 104 (91%) eyes, 20/40 for 112 (98%) eyes with 2 eyes not reported. Two (2%) eyes had a one-line drop in visual acuity for contact lenses compared to best refraction, no eyes had a two-line drop or worse. The percentage of eyes that achieved uncorrected visual acuity of 20/20 or better and 20/40 or better in relation to the initial myopia is given in the above table. A total of 46 (40%) eyes achieved a visual acuity of 20/20 or better and 87 (76 %) eyes achieved 20/40 or better.

EFFECTS ON ASTIGMATISM

Either increases or decreases in astigmatism may occur following corneal reshaping. 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 Quadra RG™ Contact Lenses for Corneal Reshaping 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:

<u>Time Worn</u>	<u>Percent of patients</u>
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 pafllufocon 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. Paflucocon B and Paflucocon 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 408 eyes (205 patients) were enrolled and treated. Data for 121 subjects (240 eyes) were analyzed following 9 months of treatment. The mean age of these subjects was 35 years (ranging from 12 to 56 years). There were 73 female and 48 male subjects comprised of 188 Caucasians, 1 African American, 13 Asian/Pacific Islanders, and 3 Hispanics. The completed subjects included adolescents and adults. There were 24 adolescent subjects that completed 9 months of treatment.

EFFECTIVENESS OUTCOMES, (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

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 study¹ 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 between 8 and 9 hours and reflected the expected distribution of night-sleep time. There was no apparent relationship between the number of hours of wear during sleep and the visual acuity outcome for any amount of pretreatment myopia.

Regression Of Visual Acuity, (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				
		-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)
REFRACTION AT LENS REMOVAL	+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.

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

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

In this trial, 408 eyes of 205 patients were evaluated for safety of paflucocon 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 measure 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 ORTHO TOOL SOFTWARE DESIGN LENSES FOR CORNEAL RESHAPING

The long-term wear of Ortho Tool Software Design Contact Lenses for Corneal Reshaping 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 Ortho Tool Software Design prescription. The wearing schedule for Ortho Tool Software Design 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 reshaping effect of myopia reduction overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving), visual fluctuations and changes in intended correction.

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
Best Spectacle Corrected Visual Acuity	Best vision you can achieve wearing glasses in your exact prescription under optimum viewing conditions
Biomicroscope	An instrument that uses magnification to examine the eye
Contact Lens Corneal Refractive Therapy	Contact lens fitting procedure that results in a reduction of nearsightedness while lenses are worn and for a temporary
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 Reshaping	Predecessor to Contact Lens Corneal Refractive Therapy using a series of lenses to achieve a temporary reduction in myopia
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
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

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