Considering Contact Lens Corneal Refractive Therapy?

Patient Information Booklet for Potential Users of
Paragon Z CRT and Paragon Z CRT Dual Axis
Contact Lenses for Contact Lens Corneal Refractive Therapy

PATIENT INFORMATION BOOKLET
FOR POTENTIAL USERS OF

Paragon Z CRT
Paragon Z CRT Dual Axis

Manufactured in Menicon Z® (tisilfocon A)

Contact Lenses For
Contact Lens Corneal Refractive Therapy
Overnight Wear

CAUTION: Federal (US) 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 contact lens fitter trained and certified in the fitting of conventional and sigmoid geometry contact lenses.

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INTRODUCTION

The information in this booklet is to help you decide whether or not to be fitted with Paragon Z CRT and Paragon Z CRT Dual Axis Contact Lenses for Corneal Refractive Therapy. Contact Lens Corneal Refractive Therapy is a fitting procedure that temporarily corrects or greatly reduces nearsightedness (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 Z CRT and Paragon Z CRT Dual Axis Contact Lenses for 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 contact lens fitter trained and certified in the fitting of conventional and sigmoid geometry contact lenses.

HOW THE EYE FUNCTIONS

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

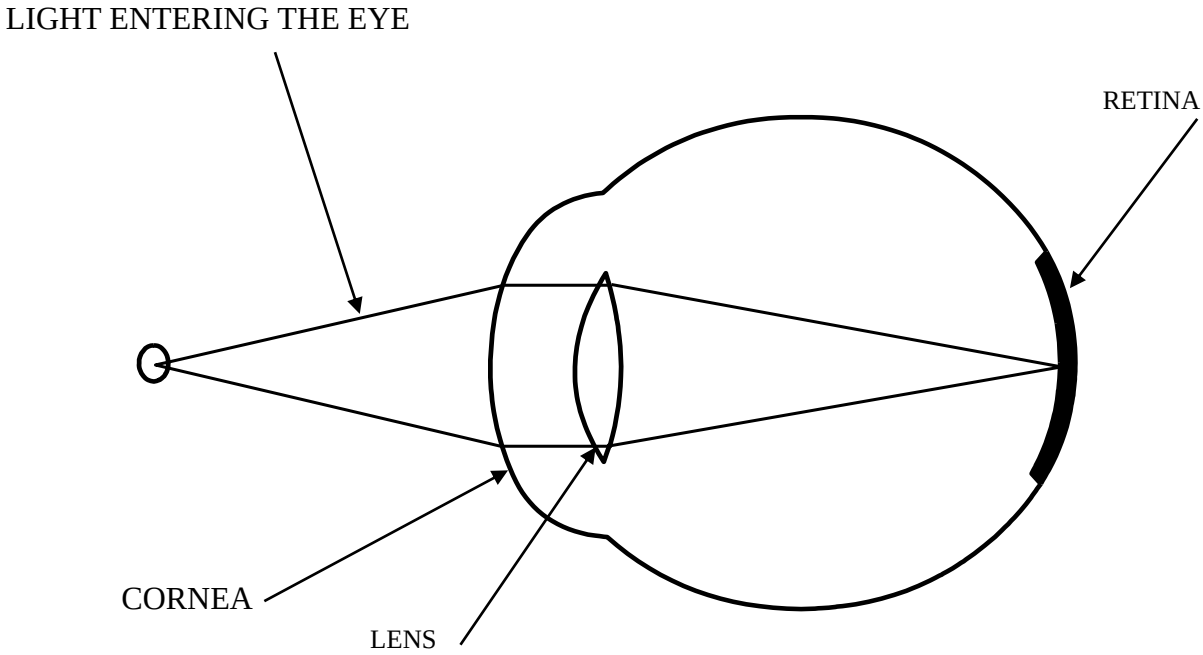

Figure 1: Normal Eye

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).

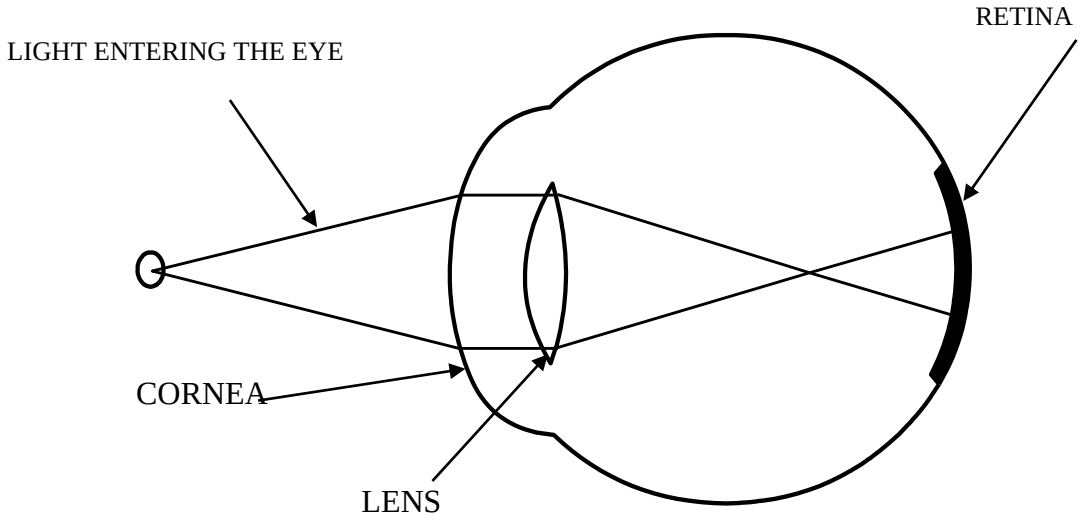

Figure 2: Nearsighted Eye

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 PARAGON Z CRT and Paragon Z CRT Dual Axis CONTACT LENSES FOR 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 Z CRT and Paragon Z CRT Dual Axis Contact Lenses for 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).

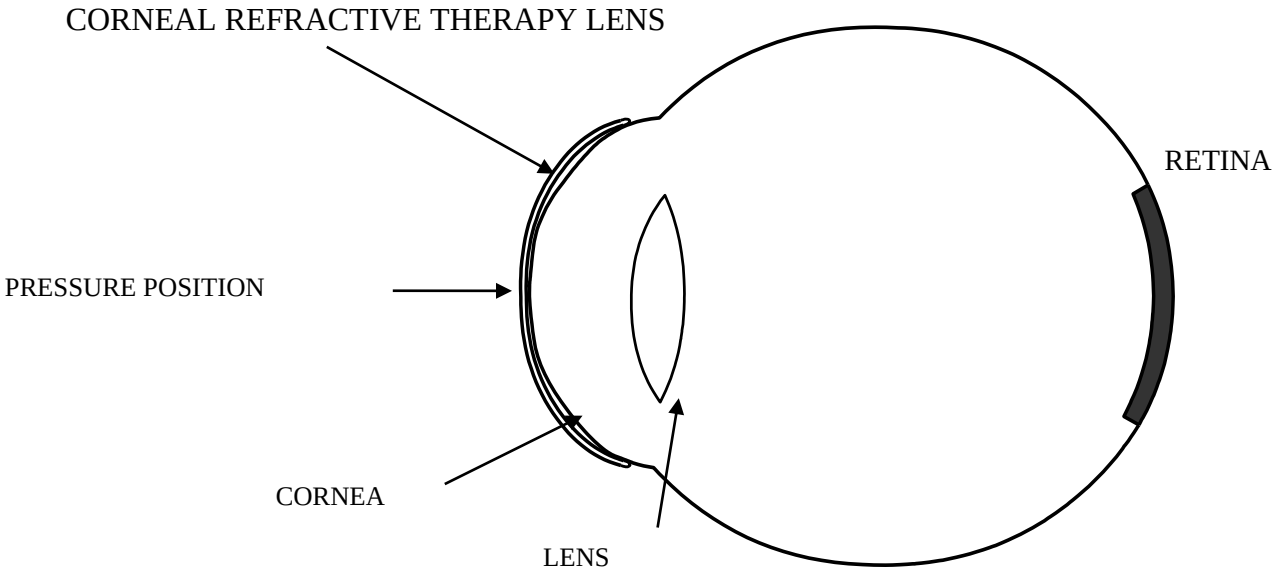

Figure 3: Eye Fitted With The CRT® Contact Lens Design For Corneal Refractive Therapy

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).

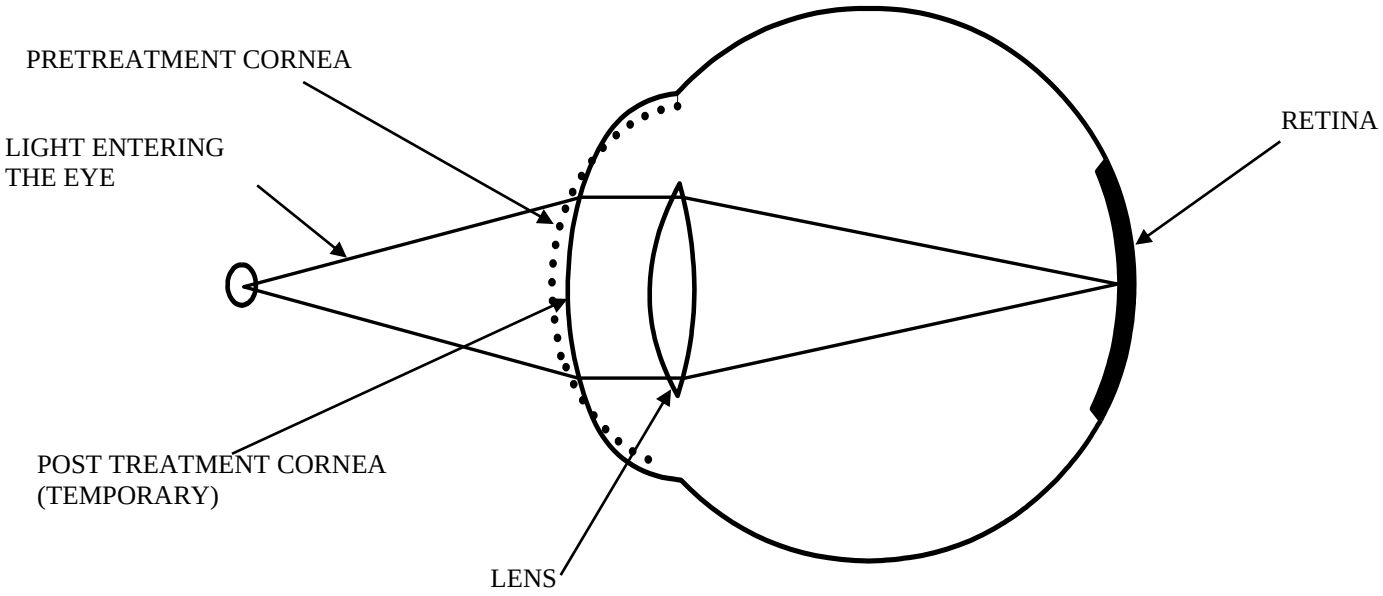

Figure 4: Nearsighted Eye after Contact Lens Corneal Refractive Therapy

Paragon Z CRT and Paragon Z CRT Dual Axis Contact Lenses for 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 of contact lenses or spectacles. Paragon Z CRT and Paragon Z CRT Dual Axis 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 alternative methods are 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 Z CRT and Paragon Z CRT Dual Axis Contact Lenses for Corneal Refractive Therapy 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 (swelling) and corneal staining (e.g. abrasion). It is anticipated that these two side effects will also occur in some wearers of Paragon Z CRT and Paragon Z CRT Dual Axis Contact Lenses for Corneal Refractive Therapy. Other side effects, which sometimes occur in all rigid 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 Refractive Therapy 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 Z CRT and Paragon Z CRT Dual Axis (tisilfocon A) Rigid Gas Permeable Contact Lenses for Corneal Refractive Therapy are indicated for use in the reduction of myopic refractive error in nondiseased eyes. The lenses are indicated for overnight wear in a Corneal Refractive Therapy fitting program for the temporary reduction of myopia up to 6.00 diopters in eyes with astigmatism up to 1.75 diopters. The lenses may be disinfected using only a chemical disinfection system.

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

PRECAUTIONS

General

Clinical studies have demonstrated that Paragon Z CRT and Paragon Z CRT Dual Axis contact lenses manufactured from Menicon Z® 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.

Each Paragon Z CRT and Paragon Z CRT Dual Axis lens is supplied nonsterile in an individual plastic case. The lens is wet shipped in Boston SIMPLUS® solution. This solution contains poloxamine, hydroxyalklphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%). If you have

experienced a prior history of allergy to any of these ingredients, remove the lens from the solution and soak the lens 24 hours in sterile unpreserved saline prior to cleaning, disinfecting and dispensing.
*Boston SIMPLUS® is a registered trademark of Bausch & Lomb

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

You should be aware of the following precautions.

Solution Precautions

- Use only recommended solutions with the contact lenses. Different solutions cannot always be used together, and not all solutions are safe for use with all 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 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 your hand rather than between the thumb and fingers. Patients should follow the complete recommended lens rubbing and rinsing times in the product labeling to adequately disinfect their lenses and reduce the risk of contact lens contamination. Reduced rubbing or rinsing times may not adequately clean their lenses.

Lens Wearing Precautions

- CAUTION: Clean and condition lenses prior to use. Lenses come non-sterile.

- If the lens sticks (stops moving) on the eye, follow the recommended directions on "Care for a Sticking Lens" in the Instructions for Wearers booklet. The lens should move freely on the eye for the continued health of the eye. If nonmovement of the lens continues, you should immediately consult your eye care practitioner.

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

- 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:

- Wearing 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 Z CRT and Paragon Z CRT Dual Axis 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 lense• Any active corneal infection (bacterial, fungal or viral)
- If eyes become red or irritated

WARNINGS

Incorrect use of contact lenses and lens care products can result in serious injury to the eye. It is essential for you 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 you experience eye discomfort, excessive tearing, vision changes, or redness of the eye, immediately remove the lenses and do not wear them until instructed to do so by the eye care practitioner. You should see your eye care practitioner according to the schedule you were given.

Paragon Z CRT and Paragon Z CRT Dual Axis 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)

You should know 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 you notice any of these conditions, IMMEDIATELY REMOVE THE LENSES and 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. 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.

SUMMARY OF CLINICAL STUDY

INTRODUCTION

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

DEMOGRAPHIC INFORMATION

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

EFFECTIVENESS OUTCOMES

The average amount of myopia (nearsightedness) that can be expected to be corrected is shown in Table 1. These values assessed on 137 eyes on which full correction was attempted are only averages and some patients can be expected to achieve more or less than these averages. Seven patients were given a monovision treatment. Monovision is an alternative method when bifocal correction is required where one eye is corrected for distance vision and the other eye is corrected for reading.

Table 1
AVERAGE REDUCTION IN MYOPIA (DIOPTERS) N=137*

Refractive Range and Count	Average Subjective Refraction (MRSE)	Average Myopia Reduction (MRSE)	Average Residual Subjective Refraction (MRSE)
-0.25>-1.00 N=8	-0.89	0.81+/ -0.48	-0.08+/ -0.38
-1.25>-2.00 N=40	-1.63	1.49+/ -0.45	-0.13+/ -0.40
-2.25>-3.00 N=46	-2.57	2.37+/ -0.62	-0.20+/ -0.57

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

-3.25>-4.00 N=25	-3.67	3.23+/ -0.67	-0.44+/ -0.62
-4.25>-5.00 N=13	-4.40	3.88+/ -0.67	-0.52+/ -0.60
-5.25>-6.00 N=5	-5.50	5.65+/ -0.55	0.15+/ -0.55

*All completed eyes targeted for emmetropia.

Uncorrected Visual Acuity (UCVA)

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

Paragon Z CRT® Contact Lenses for Corneal Refractive Therapy provided a temporary full reduction in some patients with up to -5.5 diopters of myopia. For patients with greater than -5.5 diopters of myopia only a partial reduction of myopia can be expected. The percentage of patients that can be expected to achieve full or partial temporary refractive reduction based on 144 [2] treated eyes is shown in Table 2.

Table 2

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

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

* N=144 for reduction (all efficacy qualified eyes)

** N=137 for Final VA (only eyes targeted for emmetropia)

Accuracy

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

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

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

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

Wearing Time

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

REGRESSION OF VISUAL ACUITY

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

The following guidance Table 3 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 your 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 you achieved immediately on lens removal after a night's wear. The bold value found in the cell identified in this way represents the average number of hours that similar patients have experienced before their refractive error has regressed to approximately -1.0 Diopter. Beneath that value is the minimum projected time for any subject in the study. This is only a guideline; every patient should test his/her vision as it relates to the requirements of their own daily schedules.

Table 3

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

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

			-1.12 to -2.00	-2.12 to -3.00	-3.12 to -4.00	-4.12 to -5.00	-5.12 to -6.00
REFRACTION AT LENS REMOVAL	+0.50	**Mean**	**163.7 Hrs**	**52.6 Hrs**	**19.8 Hrs**	**12.1 Hrs**	**16.9 Hrs**
		Minimum	9.3 Hrs	3.7 Hrs	4.3 Hrs	5.3 Hrs	5.5 Hrs
	+0.25	**Mean**	**162.3 Hrs**	**51.6 Hrs**	**18.9 Hrs**	**11.4 Hrs**	**15.9 Hrs**
		Minimum	9.3 Hrs	3.5 Hrs	4.1 Hrs	4.9 Hrs	5.1 Hrs

[4] Monocular Versus Binocular Visual Acuity as Measures of Vision Impairment and Predictors of Visual Disability, Rubin, et al, Invest Ophthalmol Vis Sci 2000; 41:3327-3334

	0.00	**Mean**	**159.4 Hrs**	**49.9 Hrs**	**17.5 Hrs**	**10.5 Hrs**	**14.4 Hrs**
		Minimum	9.2 Hrs	3.2 Hrs	3.9 Hrs	4.4 Hrs	4.7 Hrs
	-0.25	**Mean**	**153.5 Hrs**	**46.9 Hrs**	**15.5 Hrs**	**9.1 Hrs**	**12.3 Hrs**
		Minimum	9.1 Hrs	2.8 Hrs	3.4 Hrs	3.8 Hrs	4.1 Hrs
	-0.50	**Mean**	**139.7 Hrs**	**41.1 Hrs**	**12.3 Hrs**	**7.1 Hrs**	**9.5 Hrs**
		Minimum	8.5 Hrs	2.2 Hrs	2.8 Hrs	2.9 Hrs	3.1 Hrs
	-0.75	**Mean**	**103.9 Hrs**	**28.8 Hrs**	**7.5 Hrs**	**4.3 Hrs**	**5.5 Hrs**
		Minimum	5.1 Hrs	1.2 Hrs	1.6 Hrs	1.6 Hrs	1.8 Hrs

Effects On Astigmatism

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

OVERNIGHT WEAR SAFETY SUMMARY

In this trial, 196 eyes from 98 patients were evaluated for safety during six months overnight wear corneal refractive therapy when treating myopia and myopia with astigmatism. These data are a reliable indicator of the safety of these lenses 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)

After passing the dispensing and a successful day one visit, of the 204 eyes originally enrolled in the study, 35 were found, at one point or another, to have temporarily lost 2 lines of BSCVA from baseline. Additionally, eight subjects were observed to temporarily have BSCVA's of 20/40 or worse.

Five completed eyes, 3.5% (5/144) manifested a transient loss of two or more lines of BSCVA at the six month visit. All losses except one were found to be transient as they were not found to be present at the post-removal visits. In one case recovery was not documented before the eye was lost to follow-up. There were no eyes with BSCVA worse than 20/40 at the six month visit.

Although the range of durations until documented recovery was 0 to 216 days (one subject could not be returned for documentation), the median duration was 18 days. Of the 15 occurrences beyond the early fitting period none were bilateral and none worse than 20/32 in that eye. Only two of these eyes demonstrated visual acuities worse than 20/40 when first observed and they were documented to have been resolved at their next follow-up visit in 7 and 21 day respectively.

Absence of Persistent Corneal Change

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

Symptoms, Complaints and Discontinuations

Of the 98 subjects who had at least one night of treatment, 29 were discontinued prior to the six month visit. Table 4 below reports the tabulation of all 102 subjects that were discontinued prior to the six month visit and the reason for discontinuation.

Table 4

Reason for Discontinuation
(N=102 enrolled subjects)

Reason for Discontinuation	Number of Patients
Unacceptable Visual Acuity	13
Other	6
Lack of Comfort	3
Lack of Interest	5
Protocol Violation	2
Missed Visits	0
Pathology	0

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

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

Table 5 lists complaints and symptoms reported at doctor visits.

Table 5

PERCENT OF EYES EXHIBITING COMPLAINT OR SYMPTOM AT VISIT

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

Adverse Events and Complications

The following is the description of the adverse events discussed in the report: Subject 904 – peripheral corneal infiltrate – discontinued lens wear – administered medication - resolved in 7 days; Subject 1002 – two incidents of corneal infiltrates – discontinued lens wear – administered medication – each occurrence resolved in 6 days.

There were twenty-one positive reports of lens adherence in thirteen eyes of nine subjects. Only one of these eyes had lens adherence at multiple visits.

Patient Satisfaction

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

MAINTAINING EFFECTS OF PARAGON Z CRT and Paragon Z CRT Dual Axis LENSES FOR CORNEAL REFRACTIVE THERAPY

The long-term wear of Paragon Z CRT and Paragon Z CRT Dual Axis 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 the patient's Paragon Z CRT and Paragon Z CRT Dual Axis prescription.

The wearing schedule for Paragon Z CRT and Paragon Z CRT Dual Axis 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
Best Spectacle Corrected Visual Acuity (BSCVA)	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 (CRT®)	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 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
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
Giant Papillary Conjunctivitis	Allergic type of conjunctival inflammation on the under surface of the upper eyelid.
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	Nearsightedness, inability to see distant objects clearly

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 the Paragon Z CRT and Paragon Z CRT Dual Axis design 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
Stromal edema	Swelling of the cornea
Ulcerative keratitis	Damage to the cornea usually caused by a bacterial, fungal or viral infection

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